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MEDICARE PATIENT OUTCOME ASSESSMENT RESEARCH

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

JULY 11, 1988

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MEDICARE PATIENT OUTCOME ASSESSMENT RESEARCH

MONDAY, JULY 11, 1988

U.S. SENATE,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 2 p.m. in room SD-215, Dirksen Senate Office Building, Hon. George Mitchell (chairman of the subcommittee) presiding.

Present: Senators Mitchell, Rockefeller, Chafee, Heinz, and Durenberger.

[The prepared statements of Senators Bentsen, Rockefeller, Chafee, Heinz, and Durenberger appear in the appendix.]

[The press release announcing the hearing follows:]

[Press Release No. H-24, June 21, 1988]

FINANCE SUBCOMMITTEE ON HEALTH TO HOLD HEARING ON PATIENT OUTCOME ASSESSMENT RESEARCH

WASHINGTON, DC—Senator George Mitchell (D., Maine), Chairman of the Senate Finance Subcommittee on Health, announced Tuesday that the Subcommittee will hold a hearing on research efforts aimed at determining whether certain health treatment of Medicare patients is warranted. The Department of Health and Human Services is currently conducting a study, known as patient outcome assessment research, to examine the appropriateness, necessity, and effectiveness of medical treatments and procedures for Medicare recipients.

The hearing is scheduler for *Monday, July 11, 1988 at 2 p.m.* in room SD-215 of the Dirksen Senate Office Building.

Mitchell said, "The Medicare program is spending large amounts of money on the health care of our elderly. There is serious question whether a considerable amount of the care received by patients is inappropriate. This is most common when providers and purchasers of care are uncertain as to the benefit of the diagnostic procedure or therapy. We need to explore ways to reduce this uncertainty and improve the care available."

OPENING STATEMENT OF HON. GEORGE J. MITCHELL, A U.S. SENATOR FROM MAINE, CHAIRMAN OF THE SUBCOMMITTEE

Senator MITCHELL. Good afternoon, ladies and gentlemen.

This hearing begins Senate consideration of outcomes research. This is not a new area of research, but there is growing interest in increasing our investment and use of this potentially powerful tool.

Outcomes research is an assessment of the medical, social, and functional outcomes of medical interventions and procedures. It is a way to look beyond the question of what are we doing to the more important question of how we have helped the person. It is a way to assess competing forms of therapy and a way to help direct our efforts and resources toward those which are likely to produce the best in outcome. It is a way to decrease interventions that have no benefit for individuals, thereby decreasing human suffering and saving health dollars, and it is a way to use Medicare and Medicaid expenditures to improve the quality of the health are that Americans receive.

The need for this type of approach is clear. Providers of care are often unsure of the appropriate therapy, due to a lack of information comparing different therapies. Information from this program should decrease this uncertainty.

Individuals need better information concerning the risks and benefits of proposed therapies so they can be informed consumers.

Screens used by the Professional Review Organizations are now generic and able to cull out only the most blatant problems. They need finer tools if they are to effectively monitor the quality of care.

Those who pay for care are now unable to accurately determine what expenditures are unnecessary and are often forced to make across-the-board reductions which cut the good with the bad.

Legislation enacted in 1986 directs the National Center for Health Services Research to develop a patient-outcomes assessment research program. This program is in its infancy; $1.9 million was appropriated in 1988. The current proposed Senate appropriation is $7.5 million, but there is a growing consensus that this program needs much greater emphasis if its laudable goals are to be met.

I have introduced S. 2182, with the cosponsorship of many of my colleagues. It is a straightforward bill to increase the size, scope, and benefit of this research program. It increases the authorization from the current $7.5 million up to $30 million over the next 3 years.

With our oversight of the Medicare and Medicaid programs, this subcommittee has a vital interest in this program. We care about the quality of care provided and the cost of that care.

Today we will have an opportunity to hear from a distinguished group of witnesses who have an interest, a strong interest, in this research effort.

Our goal is to begin to examine the need to explore what this research can and cannot tell us, and to understand how providers, mayors and consumers may use this information.

I am pleased to be joined today by my distinguished colleague, a valuable contributor to our Nation's Health policy, Senator Rockefeller.

OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER, IV, A U.S. SENATOR FROM WEST VIRGINIA

Senator ROCKEFELLER. Thank you, Mr. Chairman.

I will put my statement in the record for the sake of time, but I would like to say, in general, that I think we spend a lot of time increasing and decreasing dollars spent on health care and far too little time assessing what the result of that might be.

As a result of last year's Budget Summit agreement, we had to cut $5.5 billion for fiscal years 1988 and 1989 out of the Medicare budget, and we did that. We didn't do it lightly, but we did it. Now we have got to know what the effect is going to be.

I welcome Patient Outcome Research as a way to make sure that Medicare and Medicaid beneficiaries continue to receive high quality medical care. I would like to know more than I do now about what high quality medical care is.

I just don't think we can keep making changes, Mr. Chairman, in the way we pay for health care without looking at what the results of those changes are.

Numbers are easy to manipulate, and there has been an emphasis on cost containment, but quality is more elusive and more important.

I welcome being on your bill with you, Mr. Chairman, and I am glad to be here with you.

Senator **Mitchell**. Thank you very much, Senator Rockefeller.

The first panel includes Dr. William Roper, the Administrator of the Health Care Financing Administration; Dr. Michael Fitzmaurice, Director of the National Center for Health Services Research and Health Care Technology Assessment of the Public Health Service; and Mr. Joseph Califano, Senior Partner with Dewey, Ballantine, Bushby, Palmer & Wood, formerly Secretary of the Department of Health and Human Services.

Gentlemen, I will begin by apologizing. A vote is underway in the Senate, so Senator Rockefeller and I will have to leave. We will resume the hearing and hear first from Dr. Roper with the return of the first member of the subcommittee, and we will go on from there, in the hopes that we can hear from you, gentlemen, and the following witnesses for whose presence we are grateful.

We will stand in recess temporarily until the vote is completed.

[Whereupon, the hearing was recessed, to be resumed shortly thereafter.]

AFTER RECESS

OPENING STATEMENT OF HON. DAVE DURENBERGER, A U.S. SENATOR FROM MINNESOTA

Senator **Durenberger**. The hearing will come to order.

I would like to begin my part of the hearing by thanking the Chair of the Committee for calling this hearing and for keeping pressure on the Department and the research community to make progress in research on medical outcomes.

If we are going to spend about $550 billion on health care next year—11 percent or plus of the Gross National Product—it seems that we know shockingly little about the necessity or appropriateness of the services that we are paying for.

We can't afford to buy all of the new technology or pay for all of the new organ transplants and as yet unheard-of medical miracles if we don't do something about eliminating the inappropriate medical care and even the less-than-appropriate medical care delivered in this country.

What we do know, from population-based studies, is that most Americans get a lot of medical care, especially surgery; some would say many times more than the people of any other nation, even those in the most advanced industrial nations.

Much of the care that Americans get is clearly valuable. We certainly want all Americans to have access to high-quality health care. At the same time, we have already learned that for some of the procedures and services there are seemingly no differences in the effects of the medical care.

And we know that in world-class medical centers like the Mayo Clinic and the Scott & White Clinic in Texas, and others, that surgery and other service-utilization rates are much lower than they are from other providers.

Studies of patient outcomes and quality of care by many doctors—I hate to start listing all of these folks, but Wennberg is usually at the top of the list, but there is Brook and Eddy and Ellwood and Rettig and Lohr and McClure, and all kinds of folks—Phil Caper, to name only a few, Nobrega, not Noriega.

(Laughter)

Senator **Durenberger**. He won't appreciate that.

But all of these studies document over and over that there are enormous variations from community to community in medical care, and that the factors that differentiate the communities are what are called styles of practice—circumstances in which physicians are trained.

Moreover, outcome studies illustrate that some procedures either should not be done at all or should be done only for specified conditions and under very specific circumstances. Studies of coronary bypass surgery are probably the best example.

The drive to get much better measures of medical care outcomes does not come from any desire to reduce America's access to health care; quite the contrary, it seems the only way we are going to be able to pay for all the health care that we need for all Americans, especially the growing number of older Americans and particularly the frail elderly, is if we all become truly smart buyers and providers of only the most appropriate and efficacious health care.

Right now we pay for what has always been done and for new procedures that seem to work, without the proper studies of benefits and results. We can't afford to do that and have sufficient resources to pay for what works best and, what makes a real difference, either in curing or quality of life.

I am delighted that Otis Bowen and Bill Roper share the Finance Committee's belief that outcomes and related health services research must be of the highest priority. I urge the Department to continue their emphasis during the transition. We don't want to have to start over when the changes occur in January, and it should be clear to all that the Finance Committee, as evidenced by these hearings, is absolutely committed to this research and to related health services research on quality such as the Institute of Medicine Study on quality.

The amount we are spending to improve consumer knowledge and professional knowledge is minuscule compared to the cost of health care throughout the Nation, or even compared to the Federal investment alone.

Our Federal research budget for health services is far below that that industry pays for theirs. For our Nation's health, for Medicare and Medicare's fiscal health, we must improve our investment in research.

So, with those opening comments, has this panel been introduced yet?

Dr. Roper. Yes, sir.

Senator **Durenberger**. Has anyone on the panel begun to speak? Do you remember where you were? (Laughing)

Dr. **Roper**. I had my mouth open, but I hadn't said my first word yet. (Laughter)

Senator **Durenberger**. Dr. Bill Roper. Why don't you proceed.

STATEMENT OF WILLIAM L. ROPER, M.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES WASHINGTON, DC

Dr. **Roper**. Thank you, sir. I am pleased to be here today, and I will summarize my statement.

As you said, Senator Durenberger, Secretary Bowen places this at the top of his agenda, and he spoke before this Committee on March 3rd on this very subject. I am pleased to extend his remarks of that day.

What we are trying to do within the Department is develop information on what works in the practice of medicine. Our initiative, which we are calling our "Effectiveness Initiative," has three parts: Research into patient outcomes, and Dr. Fitzmaurice from NCHSR will be discussing that more with you in a moment; second, enriching and sharing HCFA's clinical and claims data to encourage effectiveness research done by others; and, third, disseminating the results of this research to the medical community and to the public.

This is an ambitious agenda. It is one for which we are pleased to have your encouragement. It cuts across all health care components of the Department, and we are building on work done by a lot of people outside of government. I surely want to pay a compliment to the work that has gone before, but much more needs to be done, and done quickly.

What we want to do is transform the practice of medicine, and we want to do this in partnership with the medical community by putting good information in the hands of the people who want it most, physicians and patients. In order to explore the area of effectiveness, we have got to be concerned with the outcomes of care: rates of mortality and disease, levels of disability and cost. We want to construct a system that feeds back information on what happens when patients encounter the health care system, so that the overall system may be further improved.

There is evidence collected to date that leads us to believe that we have a long way to go in achieving a system that is fully effective. I would like to summarize briefly some of that evidence.

Modern medicine is an extraordinary work of reason. It is an elaborate system of specialized knowledge and procedural rules, and our society has benefited enormously because of the medical advance of the last few decades. Today, we have a much more scientific practice of medicine. But medicine is an art as well as a science. It has evolved through the subjective judgments of physicians and others, and it is the uncertainty that is built into the system that we seek to address.

One thing that demonstrates the uncertain nature of the practice of medicine is the clear differences in physician practice patterns observed across populations. Dr. Wennberg, who will speak to you in a minute, has done breakthrough research in that area.

A second area of research was done by the Rand Corporation, Dr. Robert Brook, Dr. Mark Chassin, and others, focuses attention through HCFA-sponsored research on the fact that some procedures which are quite valuable in treating many patients are performed unnecessarily on others. A percentage of 17 percent to 32 percent of some procedures are apparently done unnecessarily.

A third area of endeavor, pursued in a leading fashion by Dr. David Eddy of Duke University, has shown that the scientific evidence substantiating the effectiveness of many current medical practices is lacking.

I point to these three research efforts because I believe they highlight some of the important questions being examined. We are confronted with evidence of enormous variation, often without any apparent medical justification; a significant percentage of unnecessary procedures being performed, some of them very risky for the patient; and practicing physicians who often do not have access to the information they need to make good decisions, or who have information but find it difficult to interpret.

HCFA strongly believes that it has a pivotal role to play in resolving this unacceptable state of affairs. We see our role as a facilitator in encouraging research by conducting our own research, sharing useful data, providing funds, helping to ask the right questions, and serving as a coordinating focal point for many of the efforts of other parties involved.

Let me say a few words about what we are doing within HCFA itself. Our efforts are grouped into three broad areas: Enhanced data collection, increased emphasis on research by HCFA and others, and increased levels of information dissemination to physicians and the public.

In May we published our intention in the Federal Register to make available to researchers an enhanced information file on Medicare Part A data. We protect patient confidentiality by having names and other personal identifiers encrypted. This file will be of enormous value to research done all across the country.

We are also developing methods for using the data we collect in other new ways. For example, we are linking Part A and Part B data, linking our data with that from the National Institutes of Health, the National Cancer Institute, and others, and we are beginning to link our administrative data with clinical data collected through the Peer Review Organizations.

We are currently responsible for many research and demonstration projects on effectiveness. We view effectiveness research as a four-step process: Monitoring trends in health care, analyzing variations, assessing the different interventions used to treat patients, and providing feedback to physicians.

A prime example in the area of monitoring trends is our annual statistical analysis of mortality rates across the Medicare population.

In the area of assessment of interventions, we have collected statistical information abstracted from 29,000 medical records in the

Medicare population, and we are using this to look carefully at several medical conditions, including acute myocardial infarction.

Finally, we are placing increased emphasis on feedback and education through the peer review organizations, and also through professional societies, medical schools, the Public Health Service, and others.

It is not our intention to rate the performance of individual physicians; it is our intention to give out information that is useful to doctors in their practice of better medicine for their patients.

While it is still preliminary, I would like to illustrate the points I am making by sharing with you some of our findings. You have this in your testimony before you, but I will refer to the graphs here.

[Showing of graphs]

The first graph demonstrates mortality rates following coronary revascularization. It shows the death rate following bypass surgery being consistently higher than the death rate following angioplasty over a two-year period. However, after adjusting for many risk factors including age and other health conditions, the difference largely disappears. Knowing this, our next step will be to investigate which procedure works best on which patients.

If I could have the second graph——

[Change of graphs]

This graph depicts the variations we found in the probability of death following the same procedure, coronary revascularization, across several States. The graph reveals that the relative risk of a Medicare beneficiary dying over a 2-year period varies significantly across the States.

Let me hasten to add that this is highly preliminary information and ought to be used to pursue other investigations. But, these findings give you a flavor for the kind of research that we are pursuing and hope to pursue further in the future.

The most important element in our effectiveness agenda is how we plan to use the information we generate. It is critical that the information generated be shared with the medical practitioners who make decisions about patients. Practicing physicians are a vital link in this initiative. We believe they must be involved in all aspects of the effort, including determining the right questions to study, the data elements necessary for research, and how the research will be presented to the medical community.

Sharing information with the public is a goal that we strongly advocate. A step in that direction is our release last December of the mortality rates in hospitals participating in the Medicare program. We plan to revise and extend this data effort. For example, we are designing a tool for hospitals to use in adjusting for the severity of patient illness at each hospital.

Informed consumers are in everybody's best interest, and that is why later this Summer we will publish a document reporting on the level of quality in the 15,000 nursing homes that are a part of the Medicare and Medicaid programs. We are making these efforts carefully, in consultation with experts in the field, consumer groups, medical practitioners, and others.

To help us further this enterprise in effectiveness research, we believe we need the support of the public and the private sector. To help us set priorities for this effort, we are working with the American Medical Association, the Institute of Medicine, and other nationally prominent experts to identify those basic areas of medicine where there is particular uncertainty. We expect to gather such a group together this Summer.

Once priorities have been established, a second panel of experts will be identified to help us choose specific conditions, procedures, or technologies to be evaluated. We hope to convene this group this Fall.

In effectiveness research, we have before us an opportunity to enhance the quality of care rendered not only to Medicare beneficiaries but to all patients.

For this to be successful, we need to continue to build consensus with all the parties at interest. We have consulted extensively, including holding a meeting last June 6th where we assembled representatives from all the diverse groups at interest in this matter. I might hasten to add that Secretary Califano spoke at that meeting, at which there was very great consensus about the importance of the government's pursuing this agenda aggressively.

Let me say, in conclusion, that we are embarking on a major change in both the role of government in health care and the practice of medicine by physicians. For this effort to be successful, we need not only the support of the groups I have mentioned but also the support of the Congress, and I am pleased that you have chosen to hold this hearing today.

I would like to illustrate in my last graph what we hope to do in assisting doctors to practice better medicine.

[Change of graphs]

The graph on the left, the red graph, demonstrates the level of quality practiced by physicians across America. It is not our desire so much to find the doctors down in the lower left tail of the distribution and do something about them; rather, our desire is to move the whole curve to the right, to help everybody practice medicine in a better fashion.

This initiative is not a quick fix. Research is costly and time-consuming. We need your support and the support of all those involved. We look forward to working with you.

Thank you.

[The prepared statement of Dr. Roper appears in the appendix.]

Senator DURENBERGER. Thank you very much. Dr. Fitzmaurice.

STATEMENT OF MICHAEL FITZMAURICE, PH.D., DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. FITZMAURICE. Thank you, Senator Durenberger, Senator Rockefeller, and Mr. Chairman.

My name is Michael Fitzmaurice, and I have been the Director of the National Center for Health Services Research and Health Care Technology Assessment since August 1987. For the previous 15 years I held several positions in the Department of Health and Human Services dealing with research on the Medicare program, culminating in the position of acting Director of the Office of Research at the Health Care Financing Administration.

It is a great privilege for me to appear before the subcommittee today, and I am excited that my first opportunity to testify in front of you is about patient outcome research.

As you heard Dr. Roper state, this research is a departmental initiative which is extremely important to the Secretary. For it to be successful, it will take the concerted efforts of several offices in the Department, including HCFA and the National Center for Health Services Research. The expected benefits, however, to both quality of patient services and health costs should be well worth the effort.

The National Center for Health Services Research has been involved in studying the cost and quality of patient services for almost 20 years. We have consistently focused attention on better ways to measure the effectiveness of the health services delivery system and on the importance of patient outcomes in assessing quality of care.

The National Center for Health Services Research, as a research arm of the Public Health Service, utilizes the trusted methods of determining scientific merit. Our review process has mirrored those of the National Institute of Health.

The Omnibus Budget Reconciliation Act of 1986 authorizes the use of Medicare Trust Fund monies to fund patient outcome research by the National Center through fiscal year 1989. In response to this, the National Center issued a program note, which I have here for the record, that summarized the rationale for the Patient Outcome Assessment Research Program, as it is called, or POARP, and advised researchers of the interest of the National Center in funding research on this topic. The importance of this subject was evidenced by our receipt of a large number of well-designed research proposals approved by our standing study section panels.

When we received the monies in fiscal year 1988, we were able to begin funding 11 of those projects, which will take from 1 to 5 year to complete. Some of these projects focus on methodological issues in developing better ways to carry out the patient outcome studies, while others examine major concerns arising from variations in treatment, outcomes, and resource consumption.

I won't go through the list of 11 projects that I have in my testimony; let me just mention the first one:

The Dartmouth and Maine Medical Assessment Programs are collaborating on a project to determine the usefulness of insurance claims data in evaluating patient outcomes associated with surgical procedures and medical admissions to hospitals. The principal investigator on this grant is Dr. Wennberg, who will be testifying before you later today.

It was from our broad perspective in looking at the cost and quality of patient care that a number of our projects have come together to establish a direction for the Patient Outcome Assessment Research Program.

In particular, the National Center has supported a great many studies of resource allocation to the health care system, including those which contributed to the development of the DRG System. We initiated the development of small area variation analysis.

Many of our grants have concentrated on developing ways to measure severity of illness and patient outcome, methods which remain the current standards.

One of our first efforts was to complete the National Halothane Study, and to follow with the Institutional Differences Study. These studies demonstrated clearly that medical practices vary within hospitals, between hospitals, and among regions, and that these variations can result in significant differences in patient outcomes.

We have developed the field of health services research and have applied cost benefit and cost effectiveness analyses to treatments and their outcomes.

We pioneered in studies of group and individual medical decisionmaking. The National Center for Health Services Research has fostered the study and development of mechanisms of feedback and computer assisted clinical decisionmaking to discover the most efficient ways to change provider behavior.

Never before have the results of our efforts been so apparent in one major program. Our enthusiasm for POARP and the wide support it is receiving arises from the fact that the Patient Outcome Assessment Program is not only desirable but also timely and practical. It is desirable because it will improve quality, reduce uncertainty, and conserve resources. It is timely and practical because data bases to identify the problems, and the computers and software necessary to analyze the data, exist.

The methods developed in large part with NCHSR support are available for doing comparative studies, for synthesizing literature, for measuring severity of illness, quality of care, and individual health status.

Scientists—such as decision analysts, clinical epidemiologists, health economists, physicians, and others—versed in the necessary disciplines required for health services research of this type are out there in some number because of the support of these prior efforts.

The time is right for doing patient outcome research. All of the pieces are in place. What we need to focus on now is what we want to study and how best to do it.

The National Center for Health Services Research has maintained a strong reputation for relevant and valid scientific work, established by our authorizing legislation which guarantees peer review and by our own diligent efforts to encourage both investigators and peer reviewers to be independent thinkers. Because of this, we can provide a linkage for all the involved parties.

In cooperation with other agencies, including the Health Care Financing Administration, and in consultation with members of the practicing and research communities, the National Center has drafted criteria for the selection of conditions to be studied. These include:

First of all, differences among alternative treatments or settings with regard to (a) health benefits, (b) risks to the patients, (c) costs to the population.

A second criteria is the frequency and distribution in the population of these illnesses.

A third criteria is the availability of appropriate data.

A fourth criteria is the amount of unexplained variation in the medical practice patterns for the treatment of this particular illness.

These criteria are being applied to applications for research funds in the Patient Outcome Assessment Research Program and will be in the broader National Program for the Assessment of Patient Outcomes, or NPAPO, which the National Center has proposed. Both programs would use the same models to study health care uncertainties.

But the National Program for the Assessment of Patient Outcome concentrates on issues for which the use of Medicare funds might not be appropriate—for example, the treatment of younger patients. This could include conditions and procedures like hysterectomy, Caesarian delivery, otitis media, dental implants, and some procedures which, though useful for patients of all ages, might have different applicability depending upon the patient's age.

Our approach to the research includes the following activities:

First of all, multi-disciplinary Assessment teams, which include practicing physicians. After all, they are the people that we want to influence.

Second, other investigator-initiated assessments, aside from the Assessment Teams.

Third, experimental trials, as required.

Fourth, data source development and maintenance.

Fifth, training of research manpower.

And sixth, demonstrations of the effectiveness of the research products.

As research is completed under the Patient Outcome Assessment Research Program, the results will be widely disseminated and also transferred to our sister agency in the Public Health Service, the Health Resource and Services Administration, for them to assure that the findings become integrated into medical education.

It is anticipated that this base of knowledge about patient outcomes will be useful to practicing physicians, to the Health Care Financing Administration, to PROPAC, and to the Physicians Payment Review Commission, for carrying out their responsibilities, and that private third-party mayors could utilize these results as well, all serving to provide the highest quality of care in a cost effective manner.

I share the Secretary's enthusiasm for patient outcome research and look forward to continuing our research efforts and to sharing the results of our studies with you as they become available.

Thank you, Mr. Chairman. We would be pleased to answer any questions.

[The prepared statement of Dr. Fitzmaurice appears in the appendix.]

Senator MITCHELL. Thank you very much, Dr. Fitzmaurice.

We are pleased to be joined by Senator Chafee, who has consistently been an outspoken advocate for better health care for not only Medicare beneficiaries but all citizens.

Senator, do you have a statement you wish to place in the record?

Senator CHAFEE. Mr. Chairman, thank you very much for those kind words.

I have a brief statement I will just submit here for the record, and I look forward to hearing the witnesses. Thank you very much.

Senator MITCHELL. Thank you very much, Senator Chafee.

Now we will hear from Mr. Califano.

Welcome, Mr. Califano.

STATEMENT OF JOSEPH A. CALIFANO, JR., SENIOR PARTNER, DEWEY, BALLANTINE, BUSHBY, PALMER & WOOD, WASHINGTON, DC

Mr. CALIFANO. Thank you, Mr. Chairman.

I will submit my statement for the record and just make a few comments, if I may, summarizing it.

Let me just begin by saying I think the legislation you have introduced and that Senator Chafee and other members of the subcommittee have sponsored is very important. It probably holds the greatest likelihood that we are aware of for both providing higher quality of health care for our people, providing health care for all of our people, and containing health care costs.

It is time to recognize what we know and don't know about quality and cost effective care and do something about it, and your legislation will be critical in that endeavor.

Of all the tasks facing our health care system, none is more complex than finding out what medical care truly determines the medical outcome, what procedures have an impact on the ailment the patient suffers. In short, the toughest part is determining what quality care really is.

In the United States we spent about $1,800 per person on health care in 1985, the last year for which comparable figures are available, far more than the next highest outlay, Canada's $1,300, more than twice Japan's $800, and triple Great Britain's $600. Yet, in each of those nations health care is sophisticated and modern, life expectancy is at least as high as in ours, and infant mortality is lower.

We are so dazzled by the miracles of modern medicine that we tend to forget how far this century had progressed before a patient who visited a doctor had a better than even chance of being helped. And even today, despite the multi-million dollar array of tools we have placed at the doctor's disposal, the first step, correctly diagnosing the ailment, is no sure bet, and we know now that treatments for the same diagnosis vary widely.

In article published last year, Dr. John Wennberg, a pioneering researcher in this field, who will testify later, compared surgery and hospital rates in New Haven and Boston. He found that a New Haven resident is twice as likely to undergo a coronary bypass operation as a Bostonian, but only half as likely to receive a carotid endoterectomy.

Bostonians are much more likely to have knee and hip replacements; while New Haven residents have far more frequent hysterectomies and back surgery. Boston doctors will send you to the hospital for back pain, gastroenteritis, pneumonia and diabetes much more often than their colleagues in New Haven.

These disparities exist despite strong similarities between the populations of the two cities, and, more troubling, these different treatments appear to have no relation to the medical outcome for the patients treated.

But the costs spread among these divergent treatment styles is large. Medicare spends an average of 70 percent more for each beneficiary in Boston than it does for each beneficiary in New Haven. That is a heavy price to pay, when the patient's chances of being exposed to a more expensive, riskier procedure appear not to be a function of his or her condition but rather of the prevailing fashion in their medical neighborhood.

A Rand study of 4.5 million Medicare beneficiaries revealed wide and unexplained variations in surgery and hospitalization rates. For 67 of 123 medical and surgical procedures reviewed, more than half, residents of areas with the highest rate of treatment were at least three times as likely to be treated as those in areas with the lowest rates. If you lived in areas of the highest rate treatment, for the same symptoms you were 11 times more likely to get a hip operation, six times more likely to have a knee replaced, three times more likely to have coronary bypass surgery, five times more likely to get a skin biopsy.

Recently Rand meticulously analyzed variations among three of the 67 procedures: coronary angiography, endoscopy of the upper gastrointestinal tract, and carotid endotorectom. They found that 26 percent of the coronary angiographies, 28 percent of the endoscopies, and 64 percent of the carotid endotorectomies were clearly inappropriate or of uncertain value.

Perhaps most startling: The medical experts found that the inappropriate use of procedures was just about as high in areas with the highest and the lowest rates of use.

We paused just for a moment on the questions these facts raise about what we are buying. We have an expert consensus that from 26 to 64 percent of these three medical procedures were of no value or of uncertain value to the patients subjected to them. But even when we have a medical consensus that certain treatments are appropriate, we find enormous variations, some more than tenfold, in the rates to which people in different places are subjected to risky, expensive procedures with no apparent relationship to their health.

There are lots of examples, you have mentioned some, I would add coronary bypass surgery, Caesarean sections, tonsillectomies, pacemakers. In these and other stark situations of overutilization such as hysterectomies, the medical profession and the health insurers should develop consensus standards to avoid expensive and risky procedures that will not affect the health status of the patient.

Costs aside, subjecting patients to high-risk medical procedures that have little or no likelihood of affecting their health status or quality of life raises profound ethical issues.

The accumulating evidence of variations in procedures with no demonstrable effect on the health of the patients supports those experts who believe that at least 25 percent of the money we spend on health care is wasted. That is more than $125 billion this year. It is more than $25 billion in Federal taxpayer funds alone. In a Nation with 37 million citizens who do not have access to basic health insurance or care, in a Congress that agonizes over annual deficit reductions of less than that amount, in an era of increasing competitive pressure on our large corporations and unions to cut costs, such profligacy is unconscionable.

It is time for a rigorous effort to establish what procedures produce beneficial outcomes under what conditions. Establishing quality standards should be at the top of the agenda of the medical profession and hospital administrators, and it should be at the top of the agenda of the government, considering the amount of money it is spending, and your legislation will help put it there.

Our health care system is consuming an ever-increasing share of national resources. We are on a trajectory that will take total spending to 15 percent of our Gross National Product in just 12 years, $1.5 trillion. And with an elderly population projected to double in just a generation, the cost pressures will continue to accelerate into the next century.

We criticize Great Britain because they ration care over there, because after age 55 you can't get a kidney dialysis, there are no artificial hips for those over 65, and organ transplants are limited to special cases of virtually certain recovery. But we ration health care in this country today. We do it on the basis of economic wealth, and we do it on the basis of what the Congress decides to legislate or not legislate. And we have left 37 million people out of the health care system. We also have a host of procedures for which we will not pay.

Now, the kind of health care medical outcome analysis that you have called for in your legislation, Mr. Chairman, will put our health care system on a rational basis of distributing care; we will start making judgments as to whether or not people really need the procedures and not end up, hopefully, in a situation of the kind Great Britain has found itself.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Califano appears in the appendix.]

Senator MITCHELL. Thank you very much, Mr. Califano.

We will now go to questioning by the members, and in accordance with the rules of the Committee we will proceed in the order in which the Senators appeared for the hearing, and we will limit the questioning to five minutes per round.

I would like to begin, Dr. Roper, by thanking you again for coming and by apologizing for my absence during your testimony during the vote that occurred. I did review your testimony before the hearing, and I want to ask you one question about that.

I applaud your efforts to increase the effectiveness of the funds spent on Medicare. As you have pointed out, outcomes research is only part of your cost control and quality improvement program, but it is one area where it is important to have independent and, to the extent possible, scientifically valid information.

Given that fact, where do you think outcomes research should be conducted? Who should control the content of the program and how should we pay for it?

Dr. ROPER. I think, Senator, to take the end question first—How should we pay for it?—things that are important to the Medicare program like research of this sort are a justifiable expenditure from the Medicare Trust Fund. So I think Medicare dollars are well spent to this end.

Where should the research be done? I think in a variety of places. Some of this is research that is best done inhouse, meaning within the government. Some of it is to be done, I think, within the Health Care Financing Administration, by pulling together information resources that are currently at least theoretically available, but need dollars and other resources to put them into a form that we and others can use.

There is other research we need to do inhouse. My colleagues in the Public Health Service, like NCHSR, are also in a position to do other research of this sort.

I think the simple message is that there are parts of this effect that belong in the various components of HHS, but much of the research, finally, ought to be done in the private sector in academic communities, like basic research is done. This is too large an enterprise for anybody to lay claim to, and I surely don't lay exclusive claim to it in HCFA; but we think we have an important role to play.

Senator MITCHELL. All right. I will be pursuing this further with you, beyond this hearing.

I did want to ask Mr. Califano one question.

You mentioned that you wanted mayors to have as much information as possible to appropriately control costs and improve quality. That of course is the objective of the public portion of the system, but for several years we have had this controversy with HCFA, particularly with Dr. Roper's predecessors, on the extent to which the Administration was paying attention to the quality of care objective and just doing things to save costs. The origins of the PRO program, the so-called quotas and other things raise questions about that.

My question to you is, are you concerned that nonpublic mayors will do the same thing no matter how much information we provide? How do we insure that more than lip service is given to quality of care and that the whole thrust isn't just to containing costs?

Mr. CALIFANO. I think, Mr. Chairman, that by and large private mayors, like the government to some extent, have so far used relatively blunt instruments to contain costs. They have basically played musical chairs, changing the setting and moving the operation from in the hospital to out of the hospital, often through precertification of hospital stays.

Companies like Chrysler, where I chair their health care committee, think they are pretty close to the end of the road in that kind of health care cost containment.

Now I think there is tremendous focus. People are beginning to look at what procedures actually work and what don't work.

The reason the government becomes important, the reason the National Institutes of Health become important, the reason the medical profession is critical, is that it is really doctors that have to make that determination.

Chrysler and the United Auto Workers in this last round of contract negotiations have agreed to begin on a pilot basis establishing in effect medical outcomes, setting quality standards for when particular medical procedures are appropriate or inappropriate. Where there is a strong union on the other side and a responsible employer, I don't think you will have any problem, and I think that is the case in most situations.

Second, there is enormous pressure—hard to appreciate unless you are in the medical profession, almost—in terms of medical malpractice, which puts enormous pressure on individuals to perform adequate procedures.

I think the greater danger of hurting people is if we don't embark upon a program like this and continue to waste money on useless procedures, and deny health care to people that have none.

Senator MITCHELL. Thank you very much. My time is up. Senator Rockefeller.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Senator CHAFEE. Mr. Chairman, I wonder—I have to go. With the indulgence of Senator Rockefeller, could I just ask a couple of questions?

Senator MITCHELL. Please.

Senator ROCKEFELLER. Please do.

Senator CHAFEE. I would like to ask the panel: Is there any evidence of an effort made to keep a group healthy through yielding dollars instead of drawing on insurance, or whatever it might be, and showing that that group in the end uses far less medical care? In other words, to somehow induce a group not to smoke, or to walk x-miles per day, or to observe some kind of dietary habits that would not lead to heart attacks? Has anything ever been done in that area?

Mr. CALIFANO. Johnson and Johnson has a program called "Live for Life," which I should note that I support and try to help them promote. Over a 5-year period they have applied it to 30,000 of their own employees. It is the kind of program you are talking about, changing the total environment—smoking, alcohol consumption, diet, exercise available at the plant, courses in how to eat, how to prepare food. There has been a 30 percent reduction in hospitalization for their employees and a significant reduction in health care costs.

There is a lead time on such programs, though. You have to be willing to invest in them over 2 or 3 years before you start to get the payback in a way that a businessman can see it. And the answer is, yes, of course that works.

The drop in coronary heart disease in the United States, more than half of that—and it is dramatic, it is off 30 percent since 1970—is attributable to the change in Americans' diets and the fact that Americans have quit smoking. So, these things can work.

Dr. ROPER. Senator, if I could just add, what you are asking is have we demonstrated the effectiveness of preventive services.

There have been a lot of speeches given about the value of prevention, but there are beginning to be studies of the sort that Secretary Califano notes, that do show that preventive services do help people be healthier, it does save money over time, and we are beginning to see results of that kind of research.

Senator CHAFEE. Well, thank you.

I want to thank Senator Rockefeller very much and you, Mr. Chairman. Unfortunately, I do have to go. But this is an interesting subject, and we have got some people who know a lot about it testifying. I am so glad you got them.

Thank you.

Senator MITCHELL. Thank you, Senator Chafee. Senator Rockefeller.

Senator ROCKEFELLER. Dr. Roper and Mr. Califano, just leafing through what you have said:

Joe, in your testimony you state: "Medicare spends an average of 70 percent more for each beneficiary in Boston than it does in New Haven,"—two similar cities with totally different results. You then state: "Experts now believe that at least 25 percent of the money we spend on health care is wasted"— I mean, just wasted. That is $125 billion, and $25 billion is Federal taxpayer funds alone.

Then you go on to say that: "On a trajectory, that will take total health care spending to 15 percent of our Gross National Product, $1.5 trillion in just 12 years," et cetera.

Dr. Roper's testimony states that there there is: "evidence of enormous variation often without any apparent medical justification. Practicing physicians who often do not have access to the information they need to make good decisions, or who have information but find it difficult to interpret"—extraordinary. We allocate enormous sums of money for health, because it is what we have to do, and it is right. That is what Medicare and Medicaid is all about. But we have very little information on the effectiveness of medical care.

It is sort of like the Pentagon budget—like new missiles in a pipeline. Are they good or are they bad? Do they work, or do they not work? We are talking here about doctors who don't necessarily know the best way to treat a patient. New Haven and Boston are advanced communities, I would think, in terms of medicine, but a tremendous variation in medical care exists between these two communities.

It strikes me as a very scary business. I assume that doctors' training is reasonably uniform across this country. I don't understand why it is that, given certain information, they come to such different conclusions. Does the fear of malpractice or DRG constraints account for some differences in medical practice? We are at a point where Joe Califano says we are wasting $125 billion a year. This is Pentagon-type stuff, military budget type stuff.

I am making an observation, but I would ask for comments.

Mr. CALIFANO. I am sure Dr. Roper will comment, too, but I think we have to recognize that practice fashions develop in different communities, and they develop from where the doctor goes.

I think one of the first of these studies was made in the State of Maine, Mr. Chairman, in which the surgery rate, as I recall when I was Secretary, was twice as high in the southern part of the State than it was in the northern part of the State, in part because there were twice as many surgeons, or many more surgeons. I think the more specialists you have, the more referrals you have to specialists.

The medical malpractice item is a tremendous item. I mean, it cannot be underestimated. The insurance premium is about 1 percent, so it is about $5 billion for insurance. But the tests that it encourages doctors to run for fear of being sued, and many of these procedures—my hunch is that as Dr. Roper gets into this with the Medicare statistics, where you find two or three major malpractice coverages in a certain area of practice in a city or a community, you will find a tremendous increase in procedures designed to protect other doctors against those kinds of lawsuits.

Now, doctors also just don't know. It isn't always that easy. I would think they would be very interested in dealing with this, because, as you say, the numbers are at least at the Pentagon level.

If this kind of system is put in place and we don't learn more about what really works and doesn't work, what is going to happen is that doctors' fees will be reduced, or held, or not raised as fast as they are.

A coronary bypass in this country has become very common, very common in Canada. In Canada the cost is down to about $1,200. In this country, the cost keeps rising.

So there are a lot of different things out there.

Senator **Rockefeller**. Bill?

Dr. **Roper**. If I just may add a point, Senator?

Senator **Rockefeller**. Yes.

Dr. **Roper**. I think that we do have a situation here that cries out for change. Again, we are ready to do our part.

Why is the situation as bad as it is? First of all, I think it is because we as leaders have not recognized the importance of research into the practice of medicine. We invest heavily as a nation in basic research, and I am pleased that the NIH is as well funded as it is.

My wife is Deputy Director of the National Cancer Institute. I am not trying to take their money away from them, but we have invested a tiny amount of money in comparison in assessing the difference between today's breakthrough therapy and tomorrow's new therapy. We have very sketchy information of that sort.

A second reason why we have this situation is that the medical profession has tried to avoid any hint of national standards for how to practice medicine. That's always described as"cookbook medicine," and is descried as being a terrible situation that we should all seek to avoid.

I don't want to impose absolute standards and cookbook medicine on America, but I do think my physician colleagues are the ones who stand the most to gain from better information on what works in the practice of medicine. They will be more protected against the threat of malpractice lawsuits, and their patients will do better.

I am pleased that the AMA and other medical groups are taking a supportive role in this area. I think they now realize how important this endeavor is.

Senator **Rockefeller**. Thank you, Mr. Chairman.

Senator **Mitchell**. Thank you, Senator Rockefeller. Senator Durenberger.

Senator **Durenberger**. I am just assuming, gentlemen, that at a hearing on this subject a year from now we are all going to be a lot more knowledgeable and know the right questions to ask, because it has been incredibly difficult as we enter into the issue of quality to define what we mean.

I would like to ask you to try to help us a little better than your statements did to define what it is in sort of a national sense, to define the problem a little better, and how and where we ought to set our priorities.

I was just making some notes, as you all were talking about differentials in practice styles, about unnecessary procedures, about the lack of standards, other than in a courtroom, by which to judge a particular procedure.

I wonder if one or the other of you would sort of try your hand at something at something that the folks on the outside would understand, these consumers that we are always saying are the beneficiaries that we are here to help, as we struggle with this whole issue of quality and outcomes?

When Jay and I were walking over to vote, I told him that I usually use the example when we are talking about quality that I picked up from McClure, the one about when you get your car repaired, how are you going to tell whether it has actually been repaired? And I know that is one of the issues involved here, and the practice style is another issue, and what is really necessary and is not is an issue.

What is it that we are really after here, in a little more specific sense?

Mr. Califano. Well, I think if you look at coronary bypass operations, if you have the National Heart Institute and the Veterans' Administration studies indicating that somewhere between 60 and 80 percent of those operations are unnecessary, what we are looking at is: Why subject people to a much higher risk of death on the operating table than if they are not operated on? Why subject them to an operation like that if they don't need it? And how do you identify which of the people really need it and which really don't need it? If half the pacemakers that are put in in this country are unnecessary, don't have to be put in, why subject that half of the population to a pacemaker intrusively in their body? Let us find out which half need it and which don't.

To give you two common examples: The great advantage—and let me applaud Dr. Roper and what he is trying to do in this area—the tremendous advantage and the responsibility it seems that Medicare has is that they are the largest block of information available in this country, perhaps in the world, and by making their raw material available and by providing money to researchers like some of those who will testify here today, we will find out when it is appropriate and when it is not appropriate, who these procedures work on and who they don't work on.

My last example: Why even have a tonsillectomy if you don't need it? I often say: If you want to keep your tonsils, you stay out of Fritchburg, Framingham, and Fair Haven, Massachusetts, because you are 15 times more likely to lose your tonsils there than in the rest of the State, where they are more likely to use antibiotics.

The second part of that is why it is so important for the AMA to be involved, which is, they have got to get into the question of why doctors are still performing tonsillectomies when they can give that child a pill or——

Senator Durenberger. But on the issue of the unnecessary procedures, is the objective here that at some point in time the nation is going to set up a process by which the next heart technology that comes online has to go through some sort of medically-necessary process? Would that be the ultimate objective?

Dr. ROPER. I think the goal of this effort is several fold. One is to make certain that we assess whether new technology and existing therapies are indeed efficacious. Do they achieve the results for which they are touted?

A second area of study is to determine whether or not therapies are appropriately applied. That is to say, are they used in the right circumstance, by the right kind of doctor, on the right patient? Those are different questions, but they are both important.

A point was made just a moment ago about the resources that are at our fingertips. Medicare covers 32 million people who are admitted to hospitals 10 million times a year, and who interact with doctors 250 million times a year. And we, with a little bit of doing, can integrate this into a database that is a tremendous resource for research of this sort.

For example, we now have abstracted the records of 6,000 patients who have had either bypass grafting or balloon angioplasty for blocked heart arteries. We can now look at those patients and see what outcomes they had and begin to give doctors information on what kind of patient benefits most from angioplasty and what kind ought to go ahead and have bypass grafting. That is the kind of information that is very much needed.

A lot of people around the world criticize the American health care system, but one thing we have that they don't have is this information resource.

I was in Britain in June with the National Health Service. The British have no information of this sort, because they don't collect patient-specific information, given the way their health care system is organized. Yet, they are crying for us to get ahead with this kind of information because, frankly, it would be of use to them, and to everybody else as well.

Dr. FITZMAURICE. Senator, if I could I also interject something, the variation in what we see is due probably not only to a variation in physician medical practice but also a variation in what I want when I go to see a physician. If someone else has gotten a new operation, I may think that is the best thing in the world.

What we are trying to do with consumers' tax dollars with this program is first of all to develop good, fundamental scientific information, and then disseminate it—give it to physicians and give it to consumers, to better inform them—also, feed back to physicians information about their own practices, what is happening in their own areas, and then evaluate the effects of this feedback in terms of:

Has there been a reduction in the variation in medical practices?

Has there been an improvement in patient outcomes? Do you see people living longer? Are they surviving longer?

Is there an increase in their functional status?

Are fewer people incontinent, impotent, with more activities for daily life?

Is there an improvement in their quality of life?

And is there a conservation of medical resources when you feed back this information to given area?

This patient outcome research has a lot of importance. It is important for improving quality of medical care and saving lives, it is important for increasing and maintaining functional abilities of patients—that is what I would tell consumers. Also, it helps conserve resources, and it reduces frivolous malpractice suits as a result of developing and disseminating better scientific knowledge about patient outcomes to physicians and to the public.

Dr. ROPER. Let me just add one other point. You asked what this is about. One thing it is not about, to be clear, is how much we should, as a society, spend on health care. That is a matter for public policy debate and surely is important, but what we are talking about is how best to spend the dollars we have decided in the aggregate to spend. And, we are telling you, and I think everybody agrees, we are not getting the best bang for the bucks, and we can do better.

Senator MITCHELL. Thank you very much, doctor, and thank you for your testimony.

I will say to you and the other witnesses, there may be additional questions in writing by either members present or who couldn't make it, and we hope you will respond in writing at your earliest convenience.

[The questions appear in the appendix.]

Senator MITCHELL. The next panel includes Dr. Robert Keller, Executive Director of the Maine Medical Assessment Foundation, of Augusta, ME; Dr. Paul Elwood, Chairman of the Board of InterStudy, of Excelsior, MN; and Dr. John Wennberg, Professor of Epidemiology, Dartmouth Medical School, of Hanover, NH.

Gentlemen, welcome. We look forward to hearing from you. We are going to ask you to limit your oral remarks to 5 minutes. Your full written statements will be placed in the record. When this orange light goes on here in front of me, it means you had better start thinking about wrapping up, and the red light means please bring your remarks to a conclusion so that we can have time for questions.

Dr. Keller, welcome. We look forward to hearing about the Maine Medical Assessment Foundation and its programs.

STATEMENT OF ROBERT B. KELLER, M.D., EXECUTIVE DIRECTOR, MAINE MEDICAL ASSESSMENT FOUNDATION, AUGUSTA, ME

Dr. Keller. Thank you, Senator Mitchell, and good afternoon.

I am Dr. Robert Keller, an orthopedic surgeon practicing in Belfast, Maine, and Executive Director of the Maine Medical Assessment Foundation, or MMAF.

Because it was one of the first States to mandate collection of total hospital discharge data,Maine became an ideal site for the application of the Small Area Analysis technique developed by Wennberg and Gittlesohn.

In the early 1980s, Wennberg was joined by Dr. Daniel Hanley of Brunswick, Maine, and together they were able to convince Maine doctors of the importance and value of studying variations in medical practice.

As everywhere, analysis of Maine data revealed marked variation in hospitalization for many procedures and conditions, while for others little or no variation existed.

For nonvariable conditions such as treatment of hernia and hip fracture, it was clear that physicians were in agreement regarding the appropriate treatment. However, when hospitalization rates for other conditions were shown to vary, five to ten times among different areas, it became clear that the most significant cause was uncertainty among doctors as to the best method of treatment.

Seven study groups among medical and surgical specialties were developed to analyze variations in their fields. In briefly summarizing 6 years of work, two conclusions can be drawn:

First, the educational feedback process developed by the study groups has been remarkably successful in producing reduction in rates of hospital admissions, and doing so in a manner that is controlled by the treating physician and which has no adverse effect on the quality of care.

Second, and more importantly, we learned that when consensus regarding the best method of treatment is lacking, variations in practice patterns will occur and recur. This fact is not surprising, since there is no reason to expect physicians to admit and treat patients at approximately similar rates if they are not in agreement about the most appropriate method of treatment in the first place.

The activities of the seven study groups in Maine encompass 75 percent of our hospitalizations and 77 percent of the State's health care expenditures as they relate to hospitals' and physicians' costs. The cost savings to Maine citizens, insurers, and the State and Federal Government, which have been realized as a direct result of the MMAF's activities is at least $1.5 million each year.

These savings, while important, have occurred only indirectly, since the major thrust of the MMAF if on appropriateness and quality of care, not on cost saving.

The Maine project has demonstrated clearly that physicians will voluntarily participate in and respond to programs which analyze practice variation; but we have also shown that when consensus regarding treatment does not exist, variations will occur.

Further, we recognize that in spite of our efforts we still do not know what is the right rate for variable procedures. There is no justification for assuming that the lowest rate is best, though it may cost less.

The answers to the questions raised by physicians' uncertainty and variations in practice patterns will come only through patient-oriented outcome studies such as we are discussing funding today.

Current education and medical literature fail to adequately teach and inform physicians about the long-term outcomes of many treatments—hence, the variations. Outcome studies such as the recently completed Maine prostatectomy study indicate that patients' perceptions of their treatment and their willingness to accept various degrees of risk to achieve benefits will vary markedly among different individuals.

Intuitively, physicians have always known that two different patients with the same condition may have radically different perceptions of the degree of their disability and pain and of their individual willingness to accept the risks, benefits, and expense of treatment. What we lack is a better way to measure those factors, and a method of engaging the patient centrally in the decisionmaking process, while simultaneously eliminating physician bias. Standard setting, based on current knowledge, does not solve this problem.

The listing for criteria for treatment, expected results, and potential risks may not provide the individual patient and his or her physician with adequate information regarding the ultimate utility of treatment to that individual. Outcome studies, which focus not only on the medical aspects of care but also carefully assess patients' perceptions of the benefits and changes in quality of life, both good and bad, as a result of that care provide an important step in dealing with this problem.

When we are able to accurately measure patient-oriented outcomes of medical treatments, it will become possible to develop interactive information systems with which both doctors and patients can more accurately determine the best method of treatment for the individual patient. The result will be a more focused approach to individual clinical problems, a likely decrease in frequency of many expensive medical procedures, and improved quality of care.

Since it is the goal of all participants in the health care arena to provide the highest quality of care at the lowest cost, the funding of outcome studies seems a logical and essential step in this process.

Thank you.

[The prepared statement of Dr. Keller appears in the appendix.]

Senator MITCHELL. Thank you very much, Dr. Keller.

Dr. Ellwood, welcome. We look forward to hearing from you.

STATEMENT OF PAUL M. ELLWOOD, M.D., CHAIRMAN OF THE BOARD, INTERSTUDY, EXCELSIOR, MN

Dr. ELLWOOD. Thank you for inviting me here today.

I would like to start by making three recommendations in my testimony.

First, the restructuring of the American health system which has occurred during the Seventies and Eighties, while beneficial, requires the kind of outcomes research envisioned by S. 2182 to make any further progress in containing costs and justifying the current high expenditures on medical care.

Second, in response to Senator Durenberger's question about what is quality of medical care, I believe that good quality medical care improves the quality of life of patients, and, therefore, I recommend that the Secretary of Health and Human Services be directed to include function and wellbeing information in the Medicare database.

Third, since our real objective is to get this information applied, I would suggest that the Secretary of Health and Human Services be directed to undertake demonstration projects where outcome information and analysis is used in the everyday practice of medicine, as part of the medical record of every physician.

Now, turning to the restructuring, we have restructured the organization and incentives of the American Health Maintenance Organization has become a managed care industry, with the majority of insured Americans now undergoing some kind of managed care.

These various alternative delivery systems and DRGs have been exceedingly successful in reducing hospital utilization. In 1986, hospital utilization in the United States was at an 18-year low. However, with all that has changed in the last 18 years, I am increasingly concerned about what hasn't changed, because the same year that hospital utilization hit an 18-year low, surgical operations in the United States hit an 18-year high, in fact they had just about doubled during the 18-year period.

The increasing complexity of medical care and the growing number of chronically ill patients has jeopardized every physician's ability to make sound decisions about what to do with patients. We are constantly now faced with patients with several chronic illnesses, each of them at a different stage, perhaps each patient decaying in a different way, a constant introduction of new treatments for these patients, and we simply are unable to accurately predict what the outcome of medical care is going to be for these people. Meanwhile, we continue to expend more and more money on health care.

Really, the problem is our failure to measure and to systematically analyze the effect of these choices that patients and mayors and doctors are making on the function and wellbeing of all of us.

Now, since physicians and health care professionals are generally practicing according to what they believe is right, I don't think we are dealing with a bunch of distortions that are related to money here. Every form of health care delivery system now, the alternative delivery systems and the conventional ones, are all faced with the same dilemma: they are all operating on similar scientific premises with inadequate information on what impact medical care will have on the outcome of the patient.

The HMOs are experiencing increases in coronary bypass surgery and increases in Caesarean sections, just like the rest of the health care delivery system is experiencing. So, uncertainty about the effectiveness of medical care has not been the result of some simple flaw in the organization of health care or the incentive structure; pera stroika isn't going to save the American health system. Until we have better knowledge about what the impact of the various things that we do with patients has on their life, we are at an impasse in our efforts to change the system.

Now on the second point, the matter of the quality of information that we are working with, most outcome studies that we do right now are based on claims data, they are based on the payment for doctor visits, the purchasing of tests, the readmission of a patient to a hospital, so that the results that we are looking at, the outcomes that we are looking at, are untoward outcomes.

Whereas, most people go to the doctor to improve the quality of life—they want to get back to their jobs, they want to get rid of pain, and that sort of thing—we don't measure that routinely in the Medicare database, so any research based on what we know about is happening to these patients is naturally based on rather distorted information.

Therefore, I would recommend, just as a routine part of the kind of information that is collected in PROs and so forth, that we collect quality of life information on patients. There are now instruments available that take about 5 minutes to administer that ask the kinds of questions of patients that bring patients to the doctor.

Now, finally, I would suggest that we have had difficulty in this country and elsewhere in getting the results of outcome studies applied. The studies that Mr. Califano referred to of Rand showed that even when we know, or we think we know, what is appropriate treatment, we aren't necessarily following it.

So I don't think that outcomes assessment is something for the laboratory; it is something for everyday clinical practice, because every patient we treat is really a kind of clinical trial. We ought to be in a position where we are getting information of an outcome nature on how our patient~~s are doing,~~ and also how other physicians' patients who are treating similar kinds of problems are doing, so that this outcome information becomes a regular part of medical practice and is not something that is isolated off in the laboratory.

Thank you, Mr. Chairman.

Senator Mitchell. Thank you very much, Dr. Ellwood.

Well, Dr. Wennberg, Mr. Califano has already told us what your studies show.

(Laughter)

Senator Mitchell. Did you come up with a new statement while you were listening?

(Laughter)

Dr. Wennberg. I will try to do my best.

Senator Mitchell. All right, why don't you go ahead?

STATEMENT OF JOHN E. WENNBERG, M.D., PROFESSOR OF EPIDEMIOLOGY, DARTMOUTH MEDICAL SCHOOL, HANOVER, NH

Dr. Wennberg. Thank you very much.

It is really gratifying to be here today to see this topic receiving so much attention. It is a topic which is long overdue. The problems that we are rediscovering every few years have been around for a long time.

I would like to try to put this debate in a little historic context by saying: What essentially is going on now, in my opinion, is that we have finally decided in this country to extend the mandate to evaluate the efficacy of medical care to include all the treatment options that physicians have at their disposal; namely, surgery, diagnostic tests, and other methods of treating common illnesses.

We learned in the sixties that we needed to do that for drugs. The Thalidomide tragedy told us that we simply couldn't avoid it. We set up careful procedures in this country for evaluating the outcomes of drugs. From the basis of that scientific basis of drug treatment, it is quite well known. It may not always be used, but it is well known, at least for those drugs that have gone through the new drug application.

Surgery, diagnostic tests, and the use of hospitals versus ambulatory care settings have not had that kind of evaluation, and that is what we are calling for in this program. At least, that is what I would like to see in this program.

The second point that I had in my testimony was basically to review the Boston/New Haven situation, and I guess that has been well done.

Just let me say that my calculations say that in 1982, when these statistics I have were available, basically 16 percent of the GNP was being spent on Bostonians and the equivalent, and about 9 percent on New Haven residents, to give you another way of viewing that cost difference.

Now, my third point is that the research that needs to be done is not esoteric, is not difficult, and there are plenty of paradigms around about how to do it. So it is a matter of basically getting the will to do it rather than the know-how to do it.

I am not saying that there aren't methologic questions which need to be further developed; there always are. But the basic approach is clearly shown to us by the way we assess drugs. We do very early phase-1 and phase-2 assessments of drugs. We learn about the probabilities for outcomes for different ways of approaching a problem with drugs; and if a drug doesn't work as well as the competitor's that is already on the market, it doesn't come out. And we often know that without even having to do a randomized clinical trial—namely, the early phase-1 and phase-2 assessments clarify the theory is or is not better than another.

My proposition is that if we applied this same strategy to surgery, to alternatives to surgery such as balloon angioplasty, as it is becoming now, and to drugs across the board, we would find that many of the theories that are now being used in practice just simply don't hold up to that kind of level of scrutiny.

Dr. Keller mentioned the Maine Medical Assessment Program's work in the prostatectomy. We looked in that particular area at several theories that the physicians were using and found that one major idea, namely, operate early in order to make people live longer, simply didn't hold up to the kind of assessments that could be done.

The data showed quite the opposite—namely, that if you operate early, you lose life expectancy of a very small amount; namely, the operation is of value to people only if it improves their quality of life and they are willing to take the risk of the operation. That represents a major clarification of theory, and I believe we can do that systematically in the context of this program.

My fourth point concerns basically the principles that in my experience need to be respected as we move to remove the double standard of truth in medicine; namely, as we begin to broadly apply the principles of assessment.

The first is that the assessments must be conducted according to principles of what I call "regular science" as part of the Nation's system of peer reviewed medical research. This may seem like a simple request, but so far we have been outside of the usual domain. There hasn't been basically programs in which careers can be developed and in which individuals with interests in this kind of research can find productive careers.

I believe it is very important that we do that and we apply the principles of scientific independence, for it is the protection that assures the balanced, unbiased source of information about what is known and what remains controversial in the evolution of clinical theory.

My second principle is that the assessments must be ongoing. They simply need to take and capture new theories that come in, new ideas have to be evaluated. Assessments are an ongoing process.

Third, priorities must be set.

Now, it may seem like the problem is gigantic, and I think everyone who listens to the testimony today must throw up their hands and say, "Look, this is just too much; we can't do it." In fact, if you look carefully, there are only about 12 or 13 areas, like prostatism, like chest pain, like angina, that need to be assessed on an ongoing basis.

I have given you, in my testimony, a list of those 12 areas that I believe need this kind of ongoing assessment.

The fourth point is that regulation won't work. Innovation for most medical treatments is decentralized, grows out of the practice of medicine, out of the encounters that physicians have with their patients in their efforts to solve problems on a daily basis. We simply can't throw a big regulatory loop around it like we need new drugs.

So, we need, basically, to respect the principle of assessment teams working within the context of the innovators themselves.

Finally, rapid completion is essential.

That is my last point, and it went off the bell.

Basically, these assessments must be done in real time, they must produce useful results within the reasonable timeframe of new theory evolution, and my feeling is that if Congress invests in the National Center's Outcome Assessment Program, they can expect substantial results within two years and, after that, ongoing results every year as new theories evolve.

Finally, I would like to say I believe the physicians of this country are ready, certainly the researchers are.

My final statement would be that I would like, as a member of the Association for Health Services Research, to go on record for that organization's support for this legislation and to assure you that, if funds can be provided, the researchers of this country will go to work and help solve the problem.

[The prepared statement of Dr. Wennberg appears in the appendix.]

Senator MITCHELL. Thank you very much, Dr. Wennberg.

Let me begin, Dr. Keller, by asking you a question about the possible transferability of the voluntary approach of the Maine Medical Assessment Program to other parts of the country.

You said that there were voluntary changes in physician behavior when presented with scientific information. Have you had enough experience to know whether those changes are permanent? Is it likely that this could be transferred to other parts of the country? And are there limits to voluntary action?

Dr. KELLER. In terms of permanency, certainly in certain areas the results have been permanent. In other areas they have changed again, and that usually happens when the physician workforce changes, so that the complexity of the community changes.

But our results have shown generally that, if one brings feedback and influences physician practice patterns, it is likely to persist for a very long time.

Transferability is a very major question. As a matter of fact, there is a HCFA contract now with the AMRRC, a branch of AMPRA, which I presume will be mentioned this afternoon, that is going to attempt to spread the small area analysis technology and information to many States across the country, and we will be seeing, I think within a year, whether or not it will work.

There have been efforts in other states, particularly Arizona, which have been somewhat successful. I don't think anyone has matched the Maine program yet, but I believe that it is transferable, and the more interest that physicians have in what is going on, and the more they hear about it, the greater the degree of participation. So I would be optimistic about it.

Senator MITCHELL. Dr. Wennberg, we have heard a lot about the results of your study comparing New Haven and Boston. Has anything happened in either New Haven or Boston as a result of this study that is good for the people in either area? If not, why not? And if so, what has happened?

Dr. WENNBERG. And why not when?

Senator MITCHELL. We are often accused of answering questions we are not asked.

(Laughter)

Senator MITCHELL. I am glad to see that others do the same thing.

(Laughter)

Dr. WENNBERG. I can tell you that there is a good deal of interest in these two communities in these statistics. I must say that New Haven is happier than Boston, and I am more welcome there.

It is interesting that in conversations with the clinicians in New Haven it is quite clear that they do not feel they are rationing care. Their occupancy rates are identical with Boston, and they have more beds available if they were needed—at least that was true 2 years ago when we did the study.

The Boston situation? As far as I know, there are no efforts underway in Boston, with one exception: There was a proposal to the National Center of Health Services Research to look at the differences in pediatric admissions and also adult admissions, and unfortunately these were not funded because of lack of funds.

Senator MITCHELL. Well, in the Maine case, as Dr. Keller has indicated, you had an effort by the Maine physicians, with an organized program and some follow-through. Do you think that is an essential ingredient if we are going to have at least voluntary change on the part of physicians in their practice habit?

Dr. WENNBERG. Let me try to distinguish. There are basically two questions here. One is the question: What is the productivity and outcome differences of the various practice styles between the two communities? That is a question which can be tested and understood and the probabilities for outcomes established as a part of a scientific investigation.

The question then comes: What will happen after that information is available, when it is fed back?

What I must say is that in Boston/New Haven comparisons as yet, the efforts to establish the reasons for the big differences in medical admissions have not gotten off the ground yet. So I really can't answer the question.

Senator **Mitchell**. Do you want to comment on that, Dr. Ellwood?

Dr. **Ellwood**. Yes. I think you are missing out on a chance here, Jack, to plug your stuff. I mean, I think the reason for the persistence of these differences in frequency of these operations and so forth of the two towns is that we still don't know whether there is a difference in results, a difference in the impact on life and health of the patients as a result of these differences in use rates.

So, the doctors remain unconvinced that they need to cut down or increase the number of procedures that they are doing. We know the outcome in the number of procedures and the outcome and the number of hospitalizations, but we don't know what the effect is on patients' lives.

Senator **Mitchell**. Do you want to comment on that, Dr. Keller?

Dr. **Keller**. No, sir.

Senator **Mitchell**. All right. Thank you very much. Senator Rockefeller.

Senator **Rockefeller**. Again, Mr. Chairman, I find myself amazed by this. This is a new area for me. Dr. Keller states that the most significant cause of geographic variation is uncertainty among doctors as to the best method of treatment.

And then, Dr. Wennberg, you went on at length in your response supporting S. 2182. Then you said: "All physicians share the burden of uncertainty; they have been forced to act on behalf of their patients, using the theory and information they have and with little help from evaluative sciences; more than anyone, they want to know what is best for patients."

My understanding was that, yes, liability insurance is a problem, and that patients have different degrees or complexities of medical difficulties which make making a decision more difficult for the doctor.

But I am baffled as to why there should be so much uncertainty on the part of the physician. In other words, if there are—what?—500 DRGs, and let's say there are 1,000 or 2,000 mixes of patients with various complications, it would seem to me that it could be quantified in some way, so a doctor would be able to make a more confident decision.

On the other side, the consumer should be alert, the consumer should be more assertive and seek out the second opinion.

I suppose my question is: Insofar as there is unsureness, heavily supported by the testimony heard today, what is the responsibility of the consumer in arriving at an intelligent decision?

Consumers are the ones who are seeking medical care, who need it, and who pay for it. What is their responsibility?

Dr. **Keller**. I share your bafflement, Senator, and I think that is why we need outcome studies.

As a very quick example, laminectomy or disk low-back operations are highly variable. There are more of them done in this country than anywhere in the world—in Africa, there are almost none done. And we vary across the country, and we vary within our own State.

We have studied this problem intensively, and whenever we meet—that is, those physicians who do this kind of procedure—and talk about this problem, we do not agree. There are certain principles which we all learn as we train to be surgeons.

So we have a sort of background as to what we need to make the decision to recommend to a patient that he or she should have surgery. But beyond that there is a great deal of what is called the "threshold effect," a rather soft kind of feeling about a patient in terms of do you recommend surgery or not.

And, clearly, when we have met and discussed this subject we have not come to consensus. We have influenced the rates very nicely through peer pressure and feedback, but we have not reached consensus.

So we know that, among those things that need to be studied, disk surgery is one. There is not consensus out there.

I think patients need to know that doctors are confused, to some extent. I am sorry to have to say that, because it makes it more difficult for all of us; but the facts are that I think patients by and large think that physicians do things pretty much the same across the country. Clearly, they do not. And I think as the public becomes more aware of this problem, perhaps we will have more support in our efforts to unravel it.

Senator ROCKEFELLER. But what is the consumer to do? Most consumers, I think, look up to doctors unquestioningly. It is easy if you are in pain or have a medical problem and you are not sure or you are scared, to look up to the doctor. That is the American tradition, and I think it is a good one.

Now we learn that the doctor is uncertain about what to do. What responsibility does the consumer have, or the beneficiary have, in this process?

Dr. WENNBERG. Let me say that if neither the physician nor the patient know what the treatment is, it is a tough stand-off, isn't it? But I can say that once one clarifies what is going on, and it turns out to be that the treatment choice is a trade-off between risks of one type and benefits of another, at that point the patient can be activated right into the center of the decision process.

I must say that our assessment of prostatism in Maine led exactly to that situation.

Senator ROCKEFELLER. Can you describe that to me? With deference to the Chairman; I know the light went off.

Dr. WENNBERG. We were able, because of our assessment, to get all the chances, the probabilities, for different outcomes: the chances for becoming incontinent, for becoming impotent, of your symptoms improving, of dying from the operation, versus the chances of your symptoms staying the same if you just do nothing but take "watchful waiting," we call it. And these were very clearly different choices, with different outcomes. People basically need to have that information so they can make their choice. And that became possible as a result of the assessment. In fact, we are building that information into modern communications techniques so patients can see this information and help them understand what these chances mean.

So, assessments lead to situations where patient preferences can really be exercised in the decision process. If no one knows what the probabilities are for the different outcomes, it becomes a very dark and difficult situation, and it is very hard to know what to advise.

Senator ROCKEFELLER. Thank you, sir.

Thank you, Mr. Chairman.

Senator MITCHELL. Thank you, Senator Rockefeller. Senator Durenberger.

Senator DURENBERGER. Gentlemen, while others were asking their excellent questions, I was looking back at the 1986 conference report, because I thought we all here had some hand in initiating all of this, and I am correct.

As usual, the Senate's design won out and the House's funding, fortunately, and the administration section won out. I am wondering if you have any comments for us, first about the appropriateness of the charge. I regard we didn't have time here this afternoon to try this one on the first panel, but the first objective of the research project was to reorganize data relating to claims under Parts A and B in a manner that facilitates research with respect to patient outcome. Does anybody know whether this is being done?

Dr. WENNBERG. Yes.

Senator DURENBERGER. That is being done?

Dr. WENNBERG. Yes.

Senator DURENBERGER. The second was the assessments of the appropriateness of admissions and discharges. I take it that is just beginning.

Dr. WENNBERG. Well, that was the question about Boston and New Haven. From the technical point of view that hasn't happened, but it ought to.

Senator DURENBERGER. All right.

Third was the assessments of the extent of professional uncertainty regarding efficacy.

Dr. WENNBERG. You have heard a lot about that today.

Senator DURENBERGER. Yes, in the speeches.

Dr. WENNBERG. Right.

Senator DURENBERGER. Fourth, the development of improved methods for measuring quality of life, patient outcome. We haven't even scratched the surface.

Dr. WENNBERG. Well, it hasn't been done in that study, but just completed is a beautiful study called "The Medical Outcomes Study," where in three cities the quality of life was found to be readily measurable and easily applied to large populations.

Senator DURENBERGER. The others I think are longer. The other two are longer terms.

Let me just ask you about the current funding levels, if you have an opinion. I think the funding level for fiscal year 1987 was $4 million out of the Hospital Insurance Trust Fund and $2 million out of the SMI; for 1988, $5 million and $2.5 million; for 1989, $5 million and $2.5 million. It is like kind of a drop in the bucket compared to a lot of other research projects. Does anybody have a comment on it?

Dr. WENNBERG. I certainly would like to comment on that. (Laughter)

Senator DURENBERGER. Please.

Dr. WENNBERG. Let me say, just as a point of comparison, the drug industry, by virtue of their mandate to evaluate drugs, puts in a very large amount of money—some people think it is as high as $6 billion a year—in the development of an assessment of drug efficacy.

Senator DURENBERGER. $6 billion?

Dr. WENNBERG. Yes. That is more than we put in the NIH. It would be very useful for this Committee to find out exactly what that figure is. Compared to that, there is basically zero put into formal assessment of surgery, uses of hospitals.

So essentially what we are talking about here is redressing of a very, very large imbalance in terms of the attention paid to the evaluation of medical care outcomes.

Let me say, however, that if the strategies that we are talking about here, namely of completing these assessments using the Medicare data and the data that is available to large extent in the literature already, we are not talking about a billion-dollar problem, we are talking about a $100 million or $150 million problem.

Senator DURENBERGER. One of our problems is that we are swimming up against somebody else's billions of dollars in efficacy studies, that we are pushing against with our multi-million dollar studies.

Dr. WENNBERG. I am not sure you are competing against it, but it is just sort of a stark example of the imbalance of attention that has been paid to these two areas.

Senator DURENBERGER. Well, now that we have gone over the areas that you are supposed to be studying, how do you rate $7.5 million per year as an adequate contribution to this study? And would you have an alternative recommendation?

Dr. ELLWOOD. Well, I think it is pathetic.

Senator DURENBERGER. Pathetic? We have one for pathetic. (Laughter)

Dr. WENNBERG. I have one for $150 million.

Dr. ELLWOOD. I would say that it is easily in that range. If you just take one procedure, carotid endarterectomy, a billion and a half dollars a year we are spending on it, with no clinical trial that has demonstrated that it is efficacious, you can knock that one procedure off, which wouldn't cost any $150 million to do the studies on it, probably more in the nature of five or six, you have paid for a program like this for 10 years. And that is just the beginning. In fact, carotid endarterectomy is one of those procedures where there is a sharp contrast between Boston and New Haven, twice as likely to be done in Boston as it is in New Haven. Why?

Dr. Keller. Outcome studies are very expensive because they take a long time, relatively speaking, and they are oriented to patients. One can't just take current Medicare data and put it into a computer and create an outcome study which is oriented to patients, the kind of thing that has been illustrated by the prostatectomy study. So we certainly need much increased funding for this kind of effort.

The prostatectomy study done in Maine cost about a quarter of a million dollars, perhaps $300,000. So they are not incredibly expensive. The amount of information earned from that research effort goes well beyond the dollars spent.

Dr. ELLWOOD. I would like to put in one more plug, though for including this as a routine part of medical care, so that you are not having us sit here and try to figure out how much money ought to be spent on research on this.

The reason why we are in this problem is because we don't know what happens to patients. We simply don't know. And it seems to me that information about how patients turn out is something that we all should know.

When HCFA released its data on the death rates in hospitals, that was news to the hospitals, because they didn't know what fraction of their patients were dead 30 days later.

I think everyone who gets sick has the right to expect that the medical care system is going to know what impact medical care is having on their lives, and that that should just be a routine part of care, not a piece of research.

Senator DURENBERGER. I have one other question. I am sometimes bothered by the fact that, not Secretary Califano so much because he now represents the private sector, but everybody in that sector leans very heavily on Medicare to do its work for it, and if we don't do it well we get readily criticized.

But I am just wondering in this particular area, and given what you said about the financial resources we are putting against this. We did this in 1986 just because some knowledgeable people on the House side and over on this side said this is important work to do.

I guess I heard Secretary Califano said, "Yes, this is important work to do." But who else in the country is doing this, and where are we looking at people under 65 with regard to some of this, or where should we be? And isn't this really an effort that ought to be broader by quite a bit than just the work that is going on with the pittance we are dragging out of the two Medicare Trust Funds?

Dr. WENNBERG. Yes. I would say, for example, we don't evaluate drugs just for the over-65s. It is just as simple as that. We need to do it for everybody.

Senator DURENBERGER. Well, is there someplace we should be doing this other than where we are doing it? We're in the National Center for Health Services Research and Health Care Technology, right?

Dr. WENNBERG. Right.

Senator DURENBERGER. Is that a good place to do it across the board, that we ought to find some money to do analyses of more than Medicare information?

Dr. WENNBERG. My feeling is that the National Center represents part of the biomedical establishment, and we should support it for that reason, because this has to be part of what I call regular science, through peer review, through mechanisms in which scientists go over and make sure the data is right before it is released, so that the credibility information has the best possible peer review before it becomes available. It will void enormous confusions and counter-results.

But this is no different than biomedical science at the NIH, it is just a different topic. It is called The Evaluative Clinical Sciences.

Senator DURENBERGER. Dr. Elwood.

Dr. **Elwood**. I suspect we are going to see this whole activity take off in the private sector. I think the work that you have already done and the attention you have drawn to it has triggered it.

Just in the last few weeks I have heard from a number of major insurers, including the largest ones, who intend to now embark on programs of outcome management.

I suspect we are dealing with the same phenomena that we dealt with on HMOs. The government called attention to it, did a few demonstrations, but it was really the private sector that led the way in proving that it could be done on a wide scale. I suspect the same thing will happen here.

Senator **Mitchell**. Dr. Wennberg, when did you come down to D.C. from New Hampshire? Yesterday?

Dr. **Wennberg**. Yesterday.

Senator **Mitchell**. I notice you said $150 billion for $150 million when you were speaking, and I wondered how long it took to be in Washington before people started thinking in terms of billions.

(Laughter)

Senator **Mitchell**. Twenty-four hours in your case, right?

Dr. **Wennberg**. That's right.

(Laughter)

Senator **Mitchell**. Well, thank you all very much, gentlemen. It has been very helpful, and we look forward to working with you in this important area in the future.

The final panel includes Dr. Robert McAfee, a General Surgeon and Member of the Board of Trustees of the American Medical Associations, from South Portland, Maine, accompanied by Dr. John T. Kelly, the Director of the Office of Quality Assurance of the American Medical Association, based in Chicago; Ms. Eva Skinner, a Member of the Board of Directors of the American Association of Retired Persons, from Los Angeles; and Mr. Andrew Webber, Executive Vice President of the American Medical Peer Review Association, of Washington.

Good afternoon, ladies and gentlemen, and welcome. We look forward to hearing from you. We will begin in the order listed in the agenda, with Dr. McAfee.

As you heard me tell the prior panel, your written statements will be included in the record in full, and we ask you to limit your oral remarks to 5 minutes to permit time for questions from the members of the committee.

Dr. McAfee, welcome.

STATEMENT OF ROBERT E. McAFEE, M.D., GENERAL SURGEON AND MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, SOUTH PORTLAND, ME, ACCOMPANIED BY JOHN T. KELLY, M.D., DIRECTOR, OFFICE OF QUALITY ASSURANCE, AMERICAN MEDICAL ASSOCIATION, CHICAGO, IL, AND ROSS RUBIN, DIRECTOR OF THE AMERICAN MEDICAL ASSOCIATION'S DIVISION OF LEGISLATIVE ACTIVITIES

Dr. **McAfee**. Thank you, Mr. Chairman and members of the Committee, and thank you for the opportunity to escape the oppressive heat in coastal Maine this afternoon and be here with you in Washington.

(Laughter)

Dr. McAFEE. I am a physician in the practice of surgery in Portland, Maine, and I have been empowered by my mayor to offer our health services to those residents of Boston and New Haven who wish to come north.

(Laughter)

Dr. McAFEE. I am also a member of the Board of Trustees of the American Medical Association. With me today is Dr. John Kelly, who is Director of the AMA's Office of Quality Assurance. Accompanying us also is Ross Rubin, Director of the AMA's Division of Legislative Activities.

Let me summarize my prepared statement, Mr. Chairman.

The AMA is unequivocally committed to ensuring the provision of high quality medical care to all individuals.

High quality medical care consistently contributes to the improvement or maintenance of the quality and/or duration of life. The AMA will continue to actively foster, to pursue, and to evaluate definitions and measurement techniques for the quality of medical care in all practice settings.

As a part of this effort, we will aggressively promote organized and systematic quality assessment and quality assurance activities as an integral aspect of the day-to-day practice of every physician, regardless of the treatment setting.

AMA quality efforts, since its founding in 1847, have been based on the use of the scientific method to improve medical care, and we strongly support well-conducted quality-assessment and outcome research that will provide a better scientific basis for clinical management decisions.

When presented with well-documented data, physicians respond by adjusting their patient management practices to optimize care. Development of such data is indeed welcome.

Quality assessment and quality assurance are all part of the broad range of activities designed to assist the physician and the patient in selecting the most appropriate course of treatment for the individual patient. The AMA strongly supports these efforts.

Every day we acquire new knowledge about the human body and the most effective ways to treat disease and disability. As we expand our knowledge base, we can identify treatments that better serve our patients.

In efforts to quantify quality and effectiveness we must never lose sight, however, of the primary focus of treatment, which is the individual patient with individual needs and expectations. Patients come to the doctor one at a time.

Providing proper medical care is an enormously complex process in which many issues, subjective as well as objective, must be considered.

For example: What treatment options are available? Is there medical certainty in the area? And there is in some areas. The discussion today has suggested that we flip a coin every time we see a patient. One must understand that there is consensus now in the treatment of inguinal hernia. There is no disagreement of how one treats a hip fracture. There is no disagreement on how one treats a myocardial infarction. In the vast majority of other common conditions there is consensus, and outcomes have justified that continued consensus. It is in those areas where there is variation and uncertainty that we need the help of outcome studies.

What are the patient's expectations? And are those expectations reasonable? What individual values does the patient bring to determining the desired outcome? What quality of life issues should be considered? This was very critically important in the Maine Medical Prostatectomy Outcome Study. How should societal factors be integrated in the individual treatment decision?

Although some aspects of these issues can be quantified for research purposes, many of them cannot.

We have developed guidelines that were detailed in our full statement, Mr. Chairman, for the establishment of quality assessment systems. The key elements of these guidelines focus on physician involvement in the development of criteria used to measure quality of care and their use as an educational tool to improve physician performance.

This doesn't mean total control by physicians; what it means is physicians' involvement and participation in trying to determine these criteria. We are, however, concerned that inappropriate conclusions may be drawn and ill-advised policy decisions may be made based on the results of outcome or quality assessment research.

The complex issues involved in providing medical care to individual patients often cannot be reduced to algorithms or mathematical formulas.

In order to help ensure that the results of a quality assessment study are interpreted and used properly, the results in all cases should be subject to review and evaluation by practicing physicians through the peer review process before policy decisions are made based on those studies.

The results should be used as guides for physicians, not as absolute rules, not as cookbooks, so that physicians can tailor medical care to meet the unique medical needs of each individual patient.

The AMA has been strongly supportive of research concerning variations in utilization. We have endorsed the feedback of such data to physicians with the specialty-panel approach, and you have already heard about the Maine Medical Assessment Project. I won't continue to participate in that other than to say that it has been my privilege to be part of the advisory board of that for the last 7 years.

The appropriate utilization of any medical technology must proceed from a thorough understanding of the safety and effectiveness of that technology.

The AMA has developed and disseminated accurate and balanced evaluative information on the appropriate utilization of many medical technologies.

In furtherance of our commitment to quality care, the AMA has established an Office of Quality Assurance that will enable the Association to be a major force in the fields of quality assessment and quality assurance. The office will develop a long-range plan for quality assurance in medical care, it will coordinate existing quality activities within the AMA, it will act as a liaison with organizations with major quality assurance activities, and it will monitor and evaluate quality assurance initiatives undertaken by the AMA and other organizations.

In conclusion, Mr. Chairman, the AMA strongly supports quality assessment research. The goal of a quality assessment activity should be to educate physicians so that they can provide better patient care.

We believe strongly that outcomes research in many other areas is needed in order to assess the benefits of the treatment options available to physicians and patients, and we look forward to working with Congress and other interested parties in this important health issue.

[The prepared statement of Dr. McAfee appears in the appendix.]

Senator **Mitchell**. Thank you very much, Dr. McAfee. As always, it is a very thoughtful and informative statement.

Ms. Skinner, did you come all the way from Los Angeles?

Ms. **Skinner**. Yes, I did, last night.

Senator **Mitchell**. Did you really? Well, we especially look forward to hearing from you, then. You have come a long way. We have heard from Maine, now we will hear from California.

Ms. **Skinner**. Thank you.

STATEMENT OF EVA N. SKINNER, MEMBER, BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS, LOS ANGELES, CA, ACCOMPANIED BY STEPHANIE KENNAN, AARP FEDERAL AFFAIRS STAFF

Ms. **Skinner**. Good afternoon, Mr. Chairman.

My name is Eva Skinner, and I am a member of the AARP board of Directors. I am accompanied today by Stephanie Kennan of the AARP Federal Affairs Staff. I also serve on the Board of Directors of the Peer Review Organization For California.

As a Public Health Nurse and a Medicare beneficiary, I have both a professional and a personal interest in the outcome of medical services provided under Medicare.

Comprehensive research into the outcomes of medical treatment and procedures is long overdue. In this area of cost restraint, patient outcome research is crucial to protecting patients in maintaining access to appropriate medical care.

While AARP acknowledges and supports the effort to contain health costs, health delivery decisions should emanate from a commitment to quality assurance and not merely to cost containment.

For example, the Association believes that shorter lengths of stay do not necessarily imply inappropriate care. By the same token, high quality care is not necessarily more expensive care. Ensuring good outcomes by delivering necessary and appropriate services may in the long run save health care dollars.

Consumers need to know what they are buying with their health care dollars. To find out, we need a quality assessment and assurance system that:

(1) identifies problems in a timely way;

(2) takes corrective action;

(3) monitors the effectiveness of that action;

(4) yields data for researchers and quality of care information for the health care provider and the consumer.

Before progress can be made in assessing outcomes, we need a comprehensive database which traces the patients through the entire spectrum of care from the physician's office through recovery and post-hospital settings.

In order to do this, the Health Care Financing Administration must give priority to linkages of Parts A and B data. HCFA contractors, intermediaries, carriers, and PROs must coordinate the collection and processing of basic data elements in a uniform way to assure compatibility among providers. Also needed is the development of a patient-oriented quality assessment instrument for post-hospital care.

Variations in the use of health care services from community to community raise basic questions about the outcome of patient care.

Patient outcome assessment research must begin to account for these variations if patient outcomes are to play any role in developing policies concerning the need for care, the site of care, or payment for care. Many studies have been initiated, but much more in-depth research is needed before any conclusions can be drawn.

The Association believes that Peer Review Organizations have a central role in the development of the health care quality assurance system. PROs should be in the forefront of quality assurance research, because they represent the nation's commitment to quality in medical care.

The results of outcome research have powerful implications for both the cost and quality of health care services. While the Association envisions a range of uses for this information over time, for the foreseeable future AARP emphasizes caution in using conclusions drawn from outcome research for purposes of reimbursement.

Our limited knowledge and understanding of the subtle complexities inherent in the healing process make such use of outcome research hazardous for Medicare patients at this time. Premature use of outcome data for purposes of reimbursement could jeopardize broad-based professional support and involvement in assessing and explaining the outcomes of various treatments. Professional involvement and commitment to understanding the outcomes is critical.

Last, I want to stress the importance of translating outcomes data into understandable information to aid consumers in making more informed health care choices. A better informed patient will enhance the patient-physician relationship in the discussion of treatment.

Public disclosure of comprehensive, analyzed, and uniform data should yield a new dynamic that will lead health care providers to compete on the basis of quality. The best way to align society's expectations of medicine more closely with clinical performance is to provide more information, presented in an understandable way to the public.

Thank you, Mr. Chairman. This is a very important issue, and the Association appreciates being part of the discussion.

[The prepared statement of Ms. Skinner appears in the appendix.]

Senator MITCHELL. Thank you very much, Ms. Skinner, for a very thoughtful statement.

Mr. Webber, welcome. We look forward to hearing from you.

STATEMENT OF ANDREW H. WEBBER, EXECUTIVE VICE PRESIDENT, AMERICAN MEDICAL PEER REVIEW ASSOCIATION, WASHINGTON, DC

Mr. **Webber**. Thank you, Mr. Chairman.

I am Andy Webber, Executive Vice President of the American Medical Peer Review Association, filling in today for our President, Dr. Thomas Dean, who cannot be with us. With me is Bob Weiser, the Executive Director of KePRO, the PRO for the great State of Pennsylvania.

At the end of a long day it is hard to add anything new to the discussions that have already come before us, but let me try to summarize our statement and start with, certainly, the importance of outcome research.

I think congressional attention appropriately is shifting away from a sole focus on how we pay providers and how we need to cut Medicare expenditures to really focus on what value are we getting for our health care dollars in terms of patient outcome.

Let me say at the outset, Mr. Chairman, AMPRA is indeed in strong support of S. 2182 and will do anything that we can to see that that piece of legislation is passed.

We are hoping that a Federal commitment of dollars, and I think they are quite modest dollars and perhaps need to be increased, will also be a catalyst for the private sector to respond in kind, because I think this needs to be a partnership of both the public and private sector.

Now, the need for outcome research is quite apparent, and I will not spend a long time on it. Certainly, as we have heard today, medicine is not an exact science; there is a great degree of medical uncertainty that is reflected by the medical practice variation data that Jack Wennberg and others have put before us.

And as a result of outcome research, we really need to build greater consensus among the medical profession about whether, when, and how to treat.

Certainly this holds a great promise of both reducing health care expenditures and at the same time increasing quality of care. But let me note on caveat to that. As we have seen in the PRO program, there are many communities, particularly in rural areas—which this committee has had a lot of attention focused on—to access to care. And while in narrowing the range of medical practice we might begin to reduce overutilized areas of care, there are going to be many communities where indeed we need to increase health care services because of the access issue.

So, a result of this practice variation in outcome research will be to increase expenditures in some communities.

Now let me turn to the need for some of the quality assessment tools that I think will be the foundation for our outcome research. They have already been mentioned today and so do not need great repeating.

(1.) We need integrated databases. We need an ability, which we don't have with the fragmented Medicare database where we separated Part A from Part B, to track patients throughout the continuum of care to different care settings. We will need that ability if we are going to do the longitudinal outcome studies that are needed.

(2.) We need to collect more information. We need the routine collection of more objective clinical data on a patient's condition before, after, and during treatment if we are going to do good outcome research.

We also need, as has been mentioned before, not only clinical data; we will need functional status data, and we will need data from the individual patient as well, patient satisfaction information as well.

And let me say that in order to do this, we certainly support HCFA's development of the Uniform Clinical Data Set. I think Dr. Roper has already identified that we need more objective clinical data to be collected, and there is a project underway that we fully support to develop a uniform clinical data set for the PRO program.

With the routine collection of this information, we can go beyond the narrow and somewhat limited analyses of mortality information that has been the dominant outcome assessment focus so far. So I think we can move well beyond that.

(3.) As has been said, we need clinical trials in outcome studies, made possibly now by both an integrated database and a more comprehensive database.

Finally, we need to take the results of that clinical database and clinical outcome studies and feed that back to the physician community, and begin to develop more explicit clinical standards about when and if to treat.

Again, AMPRA urges the medical specialty societies to give guidance to the PRO community on the development of clinical guidelines if we are going to move to the final step.

Finally, let me talk about the PRO role in outcomes assessment. I think the PRO program needs to move beyond just to focus on the outliers of care and really start to impact mainstream medicine. We can do that as educators. We can disseminate information to practicing physicians on variation, on research results, on clinical guidelines.

For instance, as has been mentioned, we are involved in a project with our research affiliate The American Medical Review Research Center to take small area analysis. the complete Medicare database, and use that as a management tool to PROs.

Finally, let me say that in terms of clinical guidelines that are needed, we think clinical guidelines and clinical standards have to be applied with due care, and we think that is why local physicians are needed to make sure that these clinical standards are not applied rigidly, that there must be flexibility in how they are used.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Webber appears in the appendix.]

Senator MITCHELL. Thank you very much, Mr. Webber.

Let me ask you: You heard Dr. Keller and others describe the Maine program. Their participation is voluntary—nobody is required to participate; there are no sanctions for those who chose not to participate or to change their practice patterns. PROs operate on an entirely different principle.

Do you think that some sort of voluntary participation by physicians could on a widespread, perhaps national scale be utilized? Would you advocate such a change? How do you relate that to the principles used by PROs?

Mr. WEBBER. Certainly I would endorse any voluntary effort by the medical profession, and more experimentation of the type that is done in Maine is needed in every State.

Indeed, I think we need to move the PRO program away from just sole reliance on punitive activity to the more educational activities of which I speak.

However, the Medicare program will have to deal appropriately with appropriateness decisions at the individual claims level. And there is no doubt that this information at some point will have to be used in payment decisions.

Again, we are hoping that those clinical standards, if developed, will be applied with due care, with flexibility. But I don't think that we can get away from the notion of making decisions about appropriateness of care as they are applied to the payment decisions that the Medicare program is making.

So I don't see it as a complete substitute, and yet I think the voluntary, more educational focus is where we need to be directing our efforts, and in the PRO program as well.

Senator MITCHELL. Dr. McAfee, first let me say I am grateful for your testimony and the support of the American Medical Association for this approach. But as I am sure you have anticipated, the information will be made public. It will almost certainly be used by insurers and other payers to effect payment for medical services, perhaps at some point represent an economic interest contrary to that of the members of your Associations.

Do you think that will have some effect on how you view this?

Dr. MCAFEE. Well, I think I can only convey to you, Mr. Chairman, that the willingness to utilize this data by organized medicine, by physicians who want to do what is right, is very apparent in my travels now in my Association.

The success of the Maine project, and others—in Iowa and Maryland for example—who have had similar success, is based upon the fact that the data become very relevant to an individual physician's practice behavior.

Many of us are totally unaware where we sit in relation to our confreres. The success in Maine is because the relatively small Maine laboratory allows comparison in small areas, such that the impact of a very few physicians can significantly increase or decrease the rate of utilization.

Based upon the mutual trust and true peer review respect that physicians have for one another when sitting in that kind of environment, and looking at the fact that "I suddenly may be identified as an outlier, for doing what up to now I thought was a very appropriate kind of medical care," suddenly gets my attention.

If the data is not specific enough to allow me to make my particular practice apparent to me—that is, if this is State-wide data, or if it is regional data, or if it is even institution-wide data—it may not have nearly that much impact. The closer you get to home, the more appropriate it is to decide the appropriate issue.

I will tell you that I think there was a willingness in my organization to participate in these studies. In fact, we think it is imperative to participate in these studies to arrive at the decisions on appropriateness, and what have you.

We understand the need for publicity. But I would merely point out to you that I think the success in Maine has come because of the willingness of those who might otherwise use that data—to sensationalize, to make news, to sell newspapers—has been abrogated to allowing the physicians to have the successful program that we have had to date, and then tell the good story after the fact has been accomplished.

Senator MITCHELL. Thank you very much, Doctor.

We are pleased to be joined by Senator Heinz, who was the Chairman of the Senate Aging Committee and has been a member of this Senate Subcommittee on Health of the Committee on Finance for many years, and is one of our nation's leading policymakers in the health area.

Ordinarily when a baseball player arrives with two outs in the last half of the ninth inning, you wouldn't pay much attention to him. But if it was Babe Ruth or Hank Aaron, you would.

(Laughter)

Senator MITCHELL. This is the Babe Ruth of the health policy area, so we have to pay some attention to him. Senator Heinz.

OPENING STATEMENT OF HON. JOHN HEINZ, A U.S. SENATOR FROM PENNSYLVANIA

Senator HEINZ. Mr. Chairman, I apologize for showing up in the ninth inning. I don't even know what the count is.

Senator MITCHELL. I guess I should have said the Roberto Clemente of the health policy area.

Senator HEINZ. Mr. Chairman, your acumen and knowledge of baseball is impressive indeed. Maybe one of these days you can even get a Major League team someplace in Maine. Good luck.

(Laughter)

Senator MITCHELL. I thought you were going to say Boston.

(Laughter)

Senator HEINZ. That is a part of Maine, isn't it?

I want to apologize for having been engaged on the Senate Floor. I serve as a member of the Government Affairs Committee, and we have the Veterans' Bill up today, as you know, Mr. Chairman.

I did want to ask that my opening statement appear in the record at the appropriate point if possible, Mr. Chairman.

Senator MITCHELL. That will be done, without objection.

Senator HEINZ. And I want to commend our witnesses for their comments that I have heard.

I want to make note of the fact that earlier today Senator Mitchell and I held a press conference to release three studies: First, a New York State study on the accuracy of HCFA's hospital mortality data, and two GAO studies that I requested to get at whether there were better methods of correlating the mortality data with, in effect, outcomes.

The conclusion of those studies is that HCFA's mortality data, which is supposed to be an aid to consumers in choosing hospitals, is at best misleading and at worst somewhat dangerous, inasmuch as the study conducted by the New York State authorities indicated that hospitals with higher mortality rates—interestingly—tended to be higher quality-of-care hospitals. And HCFA was not adjusting their raw data for severity of illness or emergency admissions, and a variety of rather important considerations.

My question to Eva Skinner of AARP, is this:

Let us assume for the moment that we can improve the quality of HCFA's hospital mortality data so there is some kind of meaningful correlation between it and quality. Do we have an obligation here in the Congress and in the government to get that information into the hands of consumers as well as to make sure that it is as accurate as possible?

Ms. SKINNER. I feel that certainly we all have an obligation and that this should be part of the PROs responsibility, which they have taken and enacted quite well.

However, I think there needs to be much more information factored into the mortality data before it is released. We need to know where the patient came from before he or she was admitted to the acute hospital; we need to know what the setting is, what the complications are; we need to look more closely at age.

And this is information that needs to be presented to the consumer in a way that he and she are able to understand it.

Senator HEINZ. Let's assume that the data that HCFA released for 1987 is in fact meaningful data—that is to say that, if a hospital gets above a certain level of mortality for certain illnesses, that that is an indication of lack of quality of care. We are just assuming that; we are not stipulating that.

Ms. SKINNER. You are not accepting that; I see.

(Laughter)

Senator HEINZ. Not accepting, just assuming it for the sake of argument.

Is, the data as it is now available, presented in a way where the average senior citizen, the average member of AARP, could understand that data?

Ms. SKINNER. I think the language has to be simplified. There are still thousands and thousands of Medicare recipients out there who still don't understand the basic Medicare benefits.

I predate Medicare in terms of my involvement——

Senator HEINZ. You were born before 1964.

Ms. SKINNER. That is right, and I was a Public Health Nurse working in the field of geriatrics before 1964. I had seen over the years that there may be a little bit more understanding, but people still do not understand exactly what they are covered for.

The Catastrophic Legislation has them much more confused by now, and I think we have to really work. We need experts who can translate this information to older people in language that they themselves can accept and utilize.

Senator HEINZ. What we are talking about in this conversation is, in essence, outcomes research for hospital settings. Let me ask a question of Mr. Webber and my constituent Mr. Weiser, who represent the American Medical Peer Review Organization.

Do you believe it is feasible and prudent to begin developing outcome measures and a clinical database for assessing physician services in other than hospital settings?

Mr. Weiser. Yes, I do. I think, as we take a look at what we are going to run into in the physician setting and in other settings. Within the hospital setting there is at least some standardization of the medical records, some standardization of recordkeeping. In the physician office setting, that standardization for the most part doesn't exist. So there is no readily available database.

I think you need to begin looking right now to see how you go about developing that database, how you go about developing that standardization. It is going to be a much longer process to put into effect for the physician office and other alternative settings than it will be for the hospital.

We found that it is somewhat difficult in the hospital setting. If we don't start working in the physician office setting now, it is going to be really impossible, I think, unless we really start working at it.

Senator HEINZ. I see that my time is up.

Senator MITCHELL. Go ahead.

Senator HEINZ. What is the status of any initiatives that the PROs have underway in that area?

Mr. Weiser. Right now that is pretty much limited to inventory review of HMOs for the physician office setting. In addition, for the outpatient setting, there is a review of ambulatory surgical centers. And we have begun to move into the review of intervening care—review of SNFS, home health agencies—looking strictly at the quality side.

Part of the problem comes in integrating all of that data, which you really need to do to take a look at the whole continuum of care.

For example, in the ambulatory surgical setting, right now we cannot take the data that we get from the review and from the abstraction and integrate it with the inpatient setting, because the identification used for physicians by the Part B carrier is different than that used by the fiscal intermediary on the Part a side. So we are taking a look at how can you integrate that data.

Senator HEINZ. Are you saying that although it is difficult to build outcome data into a quality review in all its manifestations, both in-hospital and out in physician services, that nonetheless this can be done, even though there are some technical problems that have to be attended to?

Mr. Weiser. I believe it can be, yes.

Senator HEINZ. Dr. McAfee, would you agree?

Dr. MCAFEE. Well, I think that would be extremely difficult.

Let me say that our organization, the American Medical Association, which is one of the parents of the Joint Commission on Accreditation of Health Care Organizations, has sponsored and continues through the voluntary sector accreditation programs for Health Maintenance Organizations. This includes physicians' offices when they are a part of that system.

In fact, one of the reasons that we changed the name of that organization was to include the fact that it is an organization of health care, and when the physician's office is part of that organization, then indeed that setting should be part of what is accredited and assessed.

I think, however, that you already have heard that it seems to be simpler and easier to do this in a hospital setting, and I think if the standardization exists, and once the system is perfected, then I think is the time to go into a physician's office with something that we can offer, an educational motive to improve health care quality in this country, rather than to come in as a punitive—setup accordingly.

Senator HEINZ. Thank you all very much. My time has expired. I may have a few questions to submit in writing.

[Senator Heinz's questions appear in the appendix.]

Senator DURENBERGER. Just a couple of questions. I think most of you were here when I asked the question of the previous panel about the investment we are making in all of this, and I take it all of you are for this.

Does anyone disagree with the thesis that what we have here is maybe $100 million or a $150 million a year opportunity with a $7.5 million answer to it? That we really would do a better job if we would make a larger investment at this stage? Does anyone disagree with that?

Dr. McAfee?

Dr. MCAFEE. You heard the figures from our rather modest Maine follow-up study on the prostatectomy project. To do this well—that is, meeting with patients at 3 months, 6 months, 9 months, 12 months, post-surgery, and assessing the quality of life for that individual—is not an easy task. It is something that takes time. You have an independent, impartial third party who is gathering this information and feeding it back.

If you are going to do it, you have got to do it well. And to do it well does take dollars. I think $150 million for those common procedures that we have trouble with consensus with is a not unrealistic figure.

Senator DURENBERGER. Ms. Skinner?

Ms. SKINNER. I do feel that we have to place more emphasis, too, on the total picture of the illness. I mean, we can't concentrate on just the part that took place in the acute hospital. We really have no way of knowing the effectiveness unless we look at the illness from its inception until recovery at the highest level of functioning possible. And that is a rather lengthy job.

Senator DURENBERGER. We didn't get to ask Dr. Roper all of the specifics we might have liked to; but I think as I was reading this authorizing statute he had, of a year and a half, or something like that—or HCFA had a year and a half to put all of this stuff together, put it on the road, and then come back and report to us, and I assume that is what this hearing is all about—now that you have heard him testify and you are generally familiar with the course—Dr. Roper and Dr. Fitzmaurice, as well—are you generally satisfied with the direction of those who have been given responsibility to administer this program? Are you generally satisfied with the design they put together and the direction they seem to be headed?

Mr. WEBBER. Well, if I can comment, I think certainly Dr. Roper understands the critical need that is out there, and certainly with his Effectiveness Initiative there seems to be a good deal of attention focused on these issues.

I am impatient. I would like to see more done quicker. I think, again, a lot of work needs to be done in terms of integrating Medicare databases. I think work can be perhaps quickened on the development of a uniform clinical database. And certainly we need more of the outcome studies which we talked about today.

There is an urgency, particularly with Medicare, of facing critical decisions in the future about physician payment reform, about volume control on the Part B side, and we need this analysis to really buttress the decisions, the critical decisions Congress will be making in the future.

So I would hope it could happen faster. And with the investment of Federal dollars, perhaps that is a goal we could reach.

Senator DURENBERGER. Anyone else?

Dr. MCAFEE. I would like to add that the participation of practicing physicians early on we think is critical for the success of this program.

If we are to make a substantial commitment of our time and effort, and correct what we think are inequities in the health care system, we have got to be part of the players sitting at the table.

And I think to disseminate raw data without being able to massage it and utilize at least some severity index to make it meaningful is like saying the scores of the Major League ballgames today are 3 to 2, 6 to 5, 10 to 1, and 4 to 3. And it doesn't give you the information you really want to know, but it is accurate in what was given.

I think that is what we are saying. There are ways to look at this that can make very meaningful accomplishments from this very precious resource that we have.

Senator DURENBERGER. I wanted to ask you, Dr. McAfee:

I was reading one of these many high-quality health newsletters, and this one quotes Alan Einthoven on the subject we are discussing today, as follows:

"If what we are seeing in these early outcome studies holds on, old subspecialties could be put virtually out of business," he predicts.

What do you think about that?

Dr. MCAFEE. Well, I think that is a rather expansive interpretation of a few small studies.

(Laughter)

I have always enjoyed hearing Mr. Einthoven, and still look forward to him in the future, but I suspect there will be other things for doctors in some subspecialities to do in the future.

Senator DURENBERGER. Yes, that's what we are all worried about.

(Laughter)

Senator DURENBERGER. Do you have any other questions?

(No response)

Senator DURENBERGER. If not, I am sure, as I said earlier in my remarks, we are all very pleased that we are at this day, and I am sure we will be asking better questions a year from now. But we thank you all very much for your constant stimulus in getting us at this project.

Thank you very much. The hearing is adjourned.

[Whereupon, at 4:29 p.m., the hearing was concluded.]

APPENDIX

ALPHABETICAL LIST AND MATERIAL SUBMITTED

OPENING STATEMENT
HEALTH SUBCOMMITTEE HEALTH
ON PATIENT OUTCOME RESEARCH

Mr. Chairman (Senator Mitchell), I want to thank you for holding this hearing today on a topic that is probably not as well known as most of the issues we deal with in this Committee, but one that has the potential to greatly improve the health of many Americans.

This Committee has been called upon many times to save money in the Medicare and Medicaid programs, and at the same time assure the quality of the care that is provided. This is a task that requires us to seek the advice of many experts as to how we can best use the limited resources available to provide the best health care. Outcomes research is one tool that will certainly aid us in that task. If the medical and research community can develop a consensus that certain treatments in certain cases are inappropriate, ineffective, or unnecessary, then costs of the Medicare and Medicaid programs may be reduced, and the quality of the care provided will be improved. This is an outcome that we all desire.

Congress has authorized and appropriated funds to carry out this valuable research, and the Health Care Financing Administration has indicated a strong interest in this area. I am anxious to hear the witnesses today, and I am sure that this hearing will serve to improve our understanding of the research issues and policy implications involved in patient outcome assessment.

STATEMENT OF

JOSEPH A. CALIFANO, JR.*

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to testify before you today. Research on medical outcomes should be at the top of our national health research agenda. Mr. Chairman, you and other members of this subcommittee have sponsored legislation that would dramatically expand our commitment to finding out what medical procedures truly help patients and what procedures waste resources and needlessly endanger lives. I believe that enactment of this legislation is vital to the future of our health care system; it can help us improve the quality of medical care and keep it affordable for more people.

When, from the vantage point of the year 2025, the history of the American health care system is written, the 1960s will be seen as the decade of expansion of access and services and the 1980s as the decade government and private employers began to wake up to the need for cost containment and managed care. Hopefully, we'll look back on the 1990s as the decade we took on the issues of quality and effectiveness.

Many believe that cost containment efforts are the nemesis of quality medical care. A recent study even suggested that higher hospital mortality rates are related to highly regulated and highly competitive hospital markets. In my view, however, it is precisely the drive to contain costs that is fueling the next big revolution in health care -- the quality revolution.

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* Mr. Califano was Secretary of Health, Education and Welfare from 1977 to 1979, and President Lyndon Johnson's assistant for domestic affairs from 1965 to 1969. He is presently senior partner in the Washington office of the law firm of Dewey, Ballantine, Bushby, Palmer & Wood, and chairman of the health care committee of Chrysler Corporation's Board of Directors. His most recent book, America's Health Care Revolution: Who Lives? Who Dies? Who Pays?, was published by Random House in 1986.

To improve their competitive position in the marketplace, corporate managers are asking which medical procedures are truly important to their employees' health and which are simply a waste of money.

To hold down deficits and to ensure the solvency of the Medicare trust funds, the federal government wants to know whether it is reimbursing providers for ineffective or harmful treatments.

To make health care services available to the 37 million Americans who do not have health insurance and to provide long-term care to our graying population, we, as a nation, must determine how much of our half a trillion dollar a year health care spending could be safely reallocated to increase such access.

The efforts of government and the private sector to restrain costs are a "good news - bad news" story. Hospital admissions have dropped for the last three years, average length of stay dropped 22 percent in the first half of the 1980s, and for three years percentage increases in national health care spending have been in the single digits.

On the other side of the ledger, the rise in doctors' fees and services was so steep last year that Medicare increased 1988 premiums for physician care by nearly 40 percent, health care inflation rose two and one-half times as fast as the Consumer Price Index over the past two years and, this year, health insurance premiums jumped an average of almost 25 percent, with some hikes up a dizzying 70 percent.

Chrysler Corporation, where I serve as Chairman of the Board of Director's Committee on Health Care, has cut the rate of hospital admissions of its employees by almost 40 percent and the number of days in the hospital by 46 percent. At the same time, the average cost per stay paid by Chrysler has jumped almost 50 percent. To hold the line on costs, Chrysler is actively promoting HMO and PPO membership among its employees. Chrysler now has 46 percent of its employees in HMOs and PPOs where these plans are available.

So far, big purchasers have used primarily blunt instruments to hack fat out of the health care system. Hospital pre-certification, for example, tells us whether a hospital stay is needed for a certain surgical procedure or if it can be performed on an outpatient basis. It does not tell whether the proposed surgery is the right treatment for the patient's condition or if the patient has as good or better chance of recovery with less risk through drug or other medical therapy.

A preferred provider organization for laboratory tests can reduce the cost per test for an employer or insurer, but it won't tell the employer or the patient if a particular test is warranted based on the patient's symptoms and the risks and costs associated with the test. Pre-certification, preferred providers, and health maintenance organizations are referred to as "managed care," but for the most part they do not manage care; rather, they manage the setting in which care is provided.

In employers' initial efforts at cost containment, just changing the setting was often enough to produce substantial savings. Most health insurance policies had -- and many still have -- incentives for both physicians and patients to seek care in the most expensive settings. Patients had few or no incentives for cost-conscious behavior. Thus, we've been able to save by imposing or increasing deductibles and copayments for care provided in costly settings and eliminating them for care in less expensive settings.

A study just published found that private sector utilization review plans reduce hospital costs by an average of 12 percent and total medical expenditures by 8 percent. For every dollar spent on pre-certification and other controls, companies save $8.

But I believe the large consumers of health care -- government, big corporations, and big unions -- are beginning to reach the point of diminishing returns in this process of medical musical chairs where we try to get the patient to sit in the least expensive chair. We must continue to bargain for the best price for the highest quality health care services, but we must also turn our attention to the quality factor in the health care equation.

It's time to recognize what we know and don't know about quality and cost-effective care and do something about it.

Of the tasks facing our health care system, none is more complex than finding out what medical care truly determines the medical outcome, what procedures have an impact on the ailment the patient suffers. In short, the toughest part is determining what quality care really is.

We in the United States spent some $1,800 per person on health care in 1985 -- far more than the next highest outlay, Canada's $1,300, more than twice Japan's $800, and almost triple Great Britain's $600. Yet in each of those other nations, health care is sophisticated and modern. Life expectancy is at least as high as in our country and infant mortality is lower.

We are so dazzled by the miracles of modern medicine that we tend to forget how far this century had progressed before a patient who visited a doctor had a better than even chance of being helped.

Even today, despite the multi-million dollar array of tools we have placed at the doctor's disposal, the first step -- correctly diagnosing the ailment -- is no sure bet and treatments for the same diagnosis vary widely.

Evidence accumulating for more than fifteen years reveals vast unexplained differences in the rates at which patients with the same common ailments are subjected to medical procedures and hospitalization in different areas of the country, often among neighboring towns. These differences have no apparent connection with the state of health of the communities studied or the condition of the individuals treated.

In an article published last year, Dr. John Wennberg, a pioneering researcher in this field, compared surgery and hospitalization rates in New Haven and Boston. He found that a New Haven resident is twice as likely to undergo a coronary bypass operation as a Bostonian, but only half as likely to receive a carotid endarterectomy. Bostonians are much more likely to have knee and hip replacements, while New Haven residents have far more frequent hysterectomies and back surgery. Boston doctors will send you to the hospital for back pain, gastroenteritis, pneumonia, and diabetes much more often than their colleagues in New Haven. These disparities exist despite strong similarities between the populations of the two cities. More troubling, these different treatments appear to have no relation to the medical outcome for the patients treated.

But the cost spread among these divergent treatment styles is large: Medicare spends an average of 70 percent more for each beneficiary in Boston than it does in New Haven. That's a heavy price to pay when a patient's chances of being exposed to a more expensive, higher risk procedure appear not to be a function of his condition, but of the prevailing fashion in his medical neighborhood.

Exhaustive research on such disparities by Dr. Brook and his colleagues suggests both the complexity of the problem and the enormity of the opportunity. A Rand Corporation study of 4.4 million Medicare beneficiaries revealed wide and unexplained variations in surgery and hospitalization rates. For 67 of the 123 medical and surgical procedures reviewed -- more than half -- residents of areas with the highest rate of treatment were at least three times as likely to be treated as those in areas with the lowest rates. If you lived in the highest rate areas, for the same symptoms: you were eleven times more likely to get a hip operation, six times more likely to have a knee replaced, three times more likely to have coronary bypass surgery, five times more likely to get a skin biopsy.

Recently, Rand meticulously analyzed variations among 3 of the 167 procedures: coronary angiography, a surgical procedure to determine the extent of blockage of arteries serving the heart; endoscopy of the upper gastrointestinal tract, a procedure to diagnose stomach and intestinal problems; and carotid endarterectomy, surgery to remove blockages from the main artery supplying blood to the brain.

Medical experts for each procedure reviewed the research on its effectiveness and established criteria to identify circumstances when use of the procedure was clearly appropriate, clearly not appropriate, or of uncertain value. The experts then systematically applied these criteria to 5,400 case histories from 819 doctors in five different communities. They found that 26 percent of the coronary angiographies, 28 percent of the endoscopies, and 64 percent of the carotid endarterectomies were clearly inappropriate or of uncertain value.

Perhaps most startling, the medical experts found the inappropriate use of these procedures to be similarly high in areas with the highest and lowest rates of use. For instance, carotid endarterectomies were performed four times more often in the community with the highest rate than in the community with the lowest rate. But the rate of inappropriate surgery was only 1 percent higher in the highest rate area.

Pause for a moment on the troubling questions these facts raise about what we are buying for our health care dollars. We have an expert medical consensus that from 26 to

64 percent of these three medical procedures were of no value or of uncertain value to the patients subjected to them. But even when we have a medical consensus that certain treatments are appropriate, we find enormous variations -- some more than ten fold -- in the rates to which people in different places are subjected to risky, expensive surgical procedures, with no apparent relationship to their health status.

What then accounts for such stunning variations in treatment across the nation and even within the same state?

There are less than 130 medical schools in the United States, and their curricula have been pretty much standardized for fifty years. So it's doubtful that differences in medical training can be blamed. And the incidence of common ailments, such as those mentioned, does not appear to fluctuate significantly from town to town or region to region. Studies contrasting treatment of patients with similar conditions by health maintenance organizations and fee-for-service physicians offer substantial evidence that how doctors are paid influences how often they resort to surgery. But even there we have no clear idea how much of the more limited HMO surgery is appropriate.

Is it possible -- even likely -- that in this era of high-tech medicine and exotic biotechnology, we just don't know with any precision whether many procedures truly affect the medical outcome for a patient? Certainly.

But there are situations in which we should be able to develop standards of care and apply them, situations of clear overutilization. Let me suggest some.

Coronary Bypass Surgery. A series of studies by the National Institutes of Health and the Veterans Administration indicate that at least 60 percent, and possibly 80 percent, of the 250,000 Americans who submit to coronary bypass surgery each year gain no increase in life span beyond what they would have achieved through medical management of their condition with beta blockers, other modern drugs, and proper diet. Americans are four times more likely to have bypass operations than Western Europeans with the same symptoms, twice as likely as Canadians or Australians.

Cesarean Sections. Use of cesarean sections has skyrocketed, from 5.5 percent of all deliveries in 1970 to 24 percent in 1986. Medical experts estimate that at least half of the 900,000 C-sections performed in 1987 were unnecessary. The cost of these excess operations was $728 million -- for poor quality medicine. America's cesarean section rate is the highest in the industrialized world, yet we rank 17th among the world's nations in infant mortality.

Tonsillectomies. Doctors in many areas continue to perform tonsillectomies at rates far in excess of the national average. If you want to keep your tonsils, stay out of Fairhaven, Fitchburg and Framingham, Massachusetts. Residents of these cities were found to be fifteen times more likely to be subjected to tonsillectomies than residents of other Bay State communities, where antibiotics are used much more frequently to treat tonsillitis, just as effectively and much less expensively.

Pacemakers. A recent study indicates that more than half of the 120,000 pacemaker implants performed each year, at a cost of $1.5 billion, are unnecessary or of questionable value. A committee of expert physicians reviewed all pacemaker operations in Philadelphia County, Pennsylvania, over a six month period. Their study identified ignorance and fear of malpractice as the chief culprits, but noted as well that this relatively simple $12,000 operation can be highly profitable for doctors.

In these and other stark situations of overutilization, such as hysterectomies, the medical profession and the health insurers should develop consensus standards to avoid expensive and risky procedures that will not affect the health status of the patient. Costs aside, subjecting patients to high risk surgical procedures that have little or no likelihood of affecting their health status or quality of life raises profound professional and ethical issues.

I am not suggesting that all the varying judgments of doctors on what constitutes appropriate care are unreasonable, reckless, or motivated by economic self-interest. There are many situations of uncertainty, where some physicians may reasonably prefer surgery, while others may medically manage the same condition. And there are many situations where patients demand that doctors do something -- right up to the limit of their insurance coverage.

In such circumstances, we should seek to effect a major shift in physician and patient attitudes. Presently, in most cases of uncertainty about the value of a medical procedure, the physician's approach is: unless a procedure has been shown to be ineffective, try it. Patients in discomfort usually agree. Indeed, in a medical system where doctors are paid only when they do something, and patients want something done, uncertainty about diagnosis and treatment makes for all kinds of unnecessary tests and treatments.

Why not adopt a different attitude: unless the procedure has been proven effective, don't use it.

There is ample precedent for doctors and surgeons to make this cultural shift. The FDA requires that drugs be proven safe and effective before they can be marketed. Drug companies spend millions of dollars supporting years of study to demonstrate the safety and beneficial results of their products. Yet, most medical and surgical procedures -- which account for far more risk and most health care spending -- are subjected to far less scrutiny before they are adopted.

The accumulating evidence of variations in procedures with no demonstrable impact on the health of the patients supports those experts who believe that at least 25 percent of the money we spend on health care is wasted. That's more than $125 billion in 1988; it's more than $25 billion of federal taxpayer funds alone. In a nation with 37 million citizens who do not have access to basic health insurance or care, in a Congress that agonizes over annual deficit reductions of less than that amount, in an era of increasing competitive pressure on large corporations and unions to cut costs, such profligacy is unconscionable.

It's time for a rigorous effort to establish what procedures produce beneficial outcomes under what conditions. Establishing quality standards should be at the top of the agenda of the medical profession and hospital administrators; but if the profession procrastinates, then government and other big buyers of health care will act. The rocketing cost of care is spurring them to insist that reimbursement be limited to treatment that will affect the medical outcome for the patient insured.

The health care system is consuming an ever increasing share of our national resources. We are on a trajectory that will take total spending to 15 percent of our gross national product -- $1.5 trillion -- in just twelve years. And with the elderly population projected to double in just a generation, the cost pressures will continue to accelerate into the next century.

If we don't weed out the ineffective and unneeded care, we, like Great Britain, could soon be forced to ration care. We have always had rationing, of course, related to individual economic wealth. But with Medicare, the government becomes the rationer of health care for those who use and need the acute care system most.

Without the most energetic efforts to identify which medical procedures are truly effective under what circumstances, we will face a world in which there is no kidney dialysis for people over 55, no artificial hips for those over 65, and organ transplants will be limited to special cases of virtually certain recovery. In other words, unless we act, we will soon face a world of bureaucratic ~~debt~~ control.

Our obligation to forestall such a world adds a moral imperative to the practical need to eliminate the expenditure of billions of dollars for medical and surgical procedures that have absolutely no impact on the health status of the patients treated.

It is also very much in the economic self interest of American physicians to join the quest for quality care. The likely alternative for them, if the current system continues as it has to impose unnecessary procedures on patients, is a sharp restriction in the amounts government and private and insurers will pay for doctors' fees.

Some steps are being taken to determine what quality care is:

- The American College of Physicians' Clinical Efficacy Assessment project has developed more than 100 sets of guidelines for appropriate use of procedures ranging from magnetic resonance imaging to respiratory therapy.
- The Joint Commission on the Accreditation of Hospitals is developing performance indicators.
- The Pennsylvania legislature has directed the state's cost containment council to collect and publish data from every Pennsylvania doctor and hospital on the quality of care they provide: information on the incidence of surgical and medical procedures performed for what diagnoses, mortality rates, and rates of infection and hospital readmission.
- The Department of Health and Human Services is supporting research to test quality standards for hospital intensive care units and has begun to

release data from Medicare hospital bills to researchers studying health care quality and effectiveness.

Defining quality health care will not be easy. We are dealing with the best way to treat a patient, the competence of doctors, nurses and lab technicians, and many intangibles. But with computers, we can track a host of outcome measures against various medical and surgical procedures: death rates, relapses, readmissions, surgical ruptures, infections, length of hospital stays or length of time before recovery, time away from work.

At Chrysler the quest for quality health care led to a searching examination of our disability system. Chrysler found that for certain frequent surgical procedures -- like appendectomies, cataract surgery, tonsillectomies, and breast biopsies -- hourly employees were on disability leave twice as many days as expected, and much longer than salaried employees. There was wide disparity in time off the same job for the same ailments or injuries.

Chrysler, with the full cooperation of the UAW, analyzed the specific physical requirements of each of 6,000 jobs for manual dexterity, lifting and mobility. Drawing on the expertise of 47 physicians, the company examined various treatment options, depending on such factors as the employee's condition, job, age and sex. It then created guidelines for the appropriate length of disability leave.

The first year's results suggest that this program is a winner. Short-term disability claims dropped by about 20 percent during 1987 compared to 1986. For Chrysler, this program has produced savings of $5 million and more than 50,000 days of work. For employees, it has meant fewer questionable medical procedures and objective standards applied equally to all. Physicians appreciate having access to a clinically developed set of standards to judge the length of disability and resist patient pressure for more time off the job.

Because 5 percent of disability claims generate 40 percent of the costs, Chrysler and the UAW plan to target rehabilitation efforts on those employees with long-term disabilities, to help them in returning to work.

Just a few weeks ago, Chrysler and the United Auto Workers agreed to a new contract which will allow us to take another step in the direction of quality care standards. We've agreed to explore on a pilot basis a program to develop protocols for determining the necessity of specific medical services. Provider payment would be based on whether the individual patient's condition warranted the proposed treatment.

One possible model this program might follow is pre-certification for certain high volume, high cost diagnostic procedures for which there is a medical consensus on appropriate use.

To establish standards of quality care and get doctors to adopt them, we must slay the medical malpractice monster.

Medical professionals should be held accountable for negligence and incompetence, but not for our disappointment and grief over events no person can predict or control.

States should limit the amount of recovery to modest payment for pain and suffering (as California has), and largely link damages to costs of health care, replacing lost income due to inability to work, and the costs of compensating for lingering disability. Contingent legal fees should be sharply reduced.

The quest for health care quality must be pursued without imposing cookie cutter medicine and stifling the creativity and innovation that help make U.S. medicine the envy of the world. But there is much to commend standard-setting to the medical profession. For in areas where standards can be established, those standards can serve as a safe haven for doctors, protecting them from unjustified malpractice claims.

Building the research base and developing and implementing standards will be a major undertaking.

First, we must commit ourselves to providing the necessary research dollars. Dr. Robert Brook of the Rand Corporation has suggested that creating and verifying standards for the 100 most frequently used procedures would cost $100 million or more. This is a major funding commitment, but compared to the $1 billion per year we spend on cancer research and compared to the potential savings to the system and reduced risks to patients, it would be a bargain. If $100 million in research could save 10 percent of the amount we've been wasting, it would mean $10 to $12 billion in savings for our national health bill.

The increased authorization levels for outcomes research proposed by you and others, Mr. Chairman, are an important step toward building the necessary research base.

Second, we need to create a National Institute of Health Delivery, perhaps in the National Institutes of Health. The institute would be devoted to performing research to determine which medical and surgical procedures, under what circumstances, affect the health status of patients. Doctors have to have confidence in the quality and independence of the research if they are to accept new practice guidelines. The need for independence, both in fact and appearance, is particularly critical if the research findings are to be used by Medicare and other insurers to inform coverage and reimbursement decisions and if self-interested political and economic pressures are to be avoided.

There must be confidence that the research is not simply the servant of the budget cutters or of the health care industry.

Finally, we must find ways to get physicians and hospitals to adopt new standards within the medical community. Dr. Brook and his colleagues report that NIH consensus conference guidelines have little impact on actual medical practice. But other research suggests that intensive educational and monitoring programs at individual hospitals can reduce the rate of unwarranted surgery.

One voice we know doctors and hospitals will listen to is third party reimbursement. If Medicare and private insurers stop paying for procedures not used appropriately, we will surely see a drop in their use. Such decisions must be made carefully, with the benefit of the best research and the best clinical thinking. Before insurers adopt new practice standards, providers should be actively educated, as the Blues have sought to do in implementing the recommendations of the American College of Physicians.

None of us likes being second-guessed. Physicians and hospitals are already grumbling about the number of people looking over their shoulders as they try to heal the sick, deliver babies and keep up with current research and a growing avalanche of paperwork.

But a major program of research on medical effectiveness should be a boon to practitioners, allowing them to increasingly substitute science for art, intelligence for intuition, and probability for possibility. And, if we are right about the level of waste that now pervades our health care system, we can direct resources now paying for ineffective treatment to effective treatment for the millions of Americans who are without adequate health care.

Mr. Chairman, with this proposal to substantially increase outcomes research funding, I believe you have the opportunity to spark a real advance in the practice of medicine in this country, an advance that will make health care better, and make it available to more of our people.

I would be pleased to answer any questions you may have.

STATEMENT BY
SENATOR JOHN H. CHAFEE
AT
SUBCOMMITTEE ON HEALTH
ON
OUTCOME REASEARCH
JULY 11, 1988

Mr. Chairman, I am pleased that we are having this hearing on the issue of outcome reasearch. We in Congress, especially in this Committee, are faced each year with making far reaching and critical decisions on health care coverage under the Medicare and Medicaid programs. I have often expressed my concern about the effect our decisions have on our system and about the lack of information we have available when making some of those decisions.

As we deal with controlling the cost of our health care programs, it is critical that we have adequate information about the medical, social and fuctional outcomes of medical interventions. Our goal here is to provide high quality, appropriate medical services. I believe more extensive outcome reasearch will help us in that endeavor.

Consequently, I was pleased to join as a cosponsor of S. 2182, legislation to increase the authorization of funds to the National Center for Health Services Research And Technology Assessment in order further develop outcome research.

I look forward to hearing from today's witnesses. I commend the Chairman for his forsight in introducing S.2182 and for holding these hearings.

Hearing on Patient Outcome Assessment Research

Statement by

Senator Dave Durenberger

July 11, 1988

Mr. Chairman, thank you for holding this important hearing and for keeping the pressure on the department and the research community to make substantial progress in research on medical outcomes.

We will spend about $550 billion dollars on health care next year, over 11 % of the gross national product.

But we know shockingly little about the necessity or appropriateness of the services paid for. We can't afford to buy all of the new technology or pay for all of the organ transplants and yet unheard of medical miracles if we don't eliminate the inappropriate medical care and even the "less than appropriate medical care."

What we do know from population-based studies is that most americans get a lot of medical care, especially surgery-- many times more than the people of any other nation, even those in the most advanced industrial nations. Much of the care that Americans get is clearly valuable, and we certainly want all americans to have access to high quality health care. At the same time, we have already learned that for some of these procedures and services there are seemingly no differences in effects of the medical care.

And we know that in world class medical centers like the Mayo Clinic and the Scott and White Clinic in texas that surgery and other service utilization rates are much lower than they are from other providers studies of patient "outcomes," and quality of care by Drs. Wennberg, Brook, Eddy, Ellwood, Rettig, Lohr, Mcclure, Nobrega, Caper --to name only a few--document over and over that there are enormous variations from community to community in medical care and that the factors that differentiate the communities are "styles of practice" and the circumstances in which physicians are trained. Moreover, outcome studies illustrate that some procedures either should not be done at all, or should be done only for specified conditions and under very specific circumstances.

Studies of coronary-by-pass surgery are the best examples. The drive to get much better measures of medical care outcomes does not come from any desire to reduce American's access to health care. Quite the contrary, the only way that we are going to be able to pay for health care for all Americans- especially with the growing number of older Americans who are 85 and older- is if we all become truly smart buyers and providers of only the most appropriate and efficacious health care.

Right now, we pay for what has always been done and for new procedures that seem to work without the proper studies of benefits and results. We can't afford to do that and have sufficient resources to pay for what works best and what makes a real difference either in curing or quality of life.

I am delighted that Otis Bowen and Bill Roper share the Finance Committee's belief that outcomes and related health services research must be of the highest priority. I urge the department to continue this emphasis during the transition. We don't want to have to start over when the changes occur in january and it should be clear to all that the finance committee --as evidenced by these hearings--is absolutely committed to this research and to related health services research on quality such as the institute of medicine's study on quality.

The amount we are spending to improve consumer knowledge and professional knowledge is miniscule, compared to the costs of health care throughout the nation or even the federal investment alone. Our federal research budget for health services is far below what industry pays for their research. For our nation's health and for medicare and medicare's fiscal health, we must improve our investment in research.

Finally, Mr. Chairman, I am pleased to welcome Minnesota's own researcher, Dr. Paul Ellwood, who has been working on these issues for many years and whose counsel and friendship I have valued for the 10 years I have spent in the senate. His national role and the high quality of his own work have been shown once again in a recent article in the New England Journal of Medicine. Paul Ellwood remains one of the truly original thinkers in this very complicated field.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF J. MICHAEL FITZMAURICE

Mr. Chairman:
My name is J. Michael Fitzmaurice, and I have been the Director of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) since August 1987. For the previous 15 years, I held several positions in the Department of Health and Human Services (DHHS) dealing with research on the Medicare program culminating in the position of acting Director of the Office of Research at the Health Care Financing Administration (HCFA).

It is a great privilege for me to appear before the Subcommittee today and I am excited that my first opportunity to testify is about patient outcome research. As you heard Dr. Roper state this research is a Departmental initiative which is extremely important to the Secretary. For it to be successful it will take the concerted effort of several offices in the Department including HCFA and NCHSR. The expected benefits, however, to both quality patient services and health costs should be well worth the effort.

The National Center for Health Services Research has been involved in studying the cost and quality of patient services for almost twenty years. We have consistently focused attention on better ways to measure the effectiveness of the health services delivery system and on the importance of patient outcomes in assessing quality of care. NCHSR as a research arm of the Public Health Service utilizes the trusted methods of determining scientific merit.

The Omnibus Budget Reconciliation Act of 1986 authorizes the use of Medicare Trust Fund monies to fund patient outcome research by the National Center for Health Services Research through fiscal year 1989. In response to this, NCHSR issued a program note that summarized the rationale for the Patient Outcome Assessment Research Program (POARP) as it is called and advised researchers of the interest of NCHSR in funding research on this topic. The importance of this subject is evidenced by our receipt of a number of well-designed research proposals.

When we received the monies in FY '88, we were able to begin funding eleven of those projects which will take from one to three years to complete. Some of these projects focus on methodological issues in developing better ways to carry out patient outcome studies and others examine major concerns arising from variations in treatment, outcomes and resource consumption.

Briefly, these projects are as follows:

1. Dartmouth and the Maine Medical Assessment Program are collaborating on a project to determine the utility of insurance claims data in evaluating patient outcomes associated with surgical procedures and medical admissions to hospitals. (P.I. Wennberg)

2. Rand is looking at the outcomes of variation in treatments for diabetes, hypertension, and heart disease. (P.I. Greenfield)

3. George Washington University is refining a severity classification scheme designed to aid in evaluating the appropriate use of Intensive Care Units. (P.I. Knaus)

4. University of Washington is looking at varying rates of surgery for low back pain and comparing operative results with the outcomes of other methods of treatment. (P.I. Loeser)

5. Albert Einstein College of Medicine is studying the reasons for the wide variation in the number of Third Molar Extractions. (P.I. Badner)

6. University of Rochester is studying the effects of providing comprehensive feedback to physicians in improving practice patterns. (P.I. Suchman)

7. Harvard School of Public Health is developing better techniques for analyzing and synthesizing medical literature on alternative treatment methods. (P.I. Mosteller)

8. John Hopkins is examining variations in the rate of Coronary Artery Bypass Surgery and the differences in clinical outcomes among hospitals in Maryland. (P.I. Halpern)

9. Yale is testing the usefulness of a statewide data system in Connecticut for identifying and analyzing the reasons for variations in hospital use. (P.I. Legnin)

10. The University of California at San Francisco is examining reasons for differences among specialists in rheumatic diseases in their use of medical and surgical hospitalization to treat patients with rheumatoid arthritis. (P.I. Henke)

11. Finally, the University of Copenhagen in cooperation with the Danish Government is comparing the treatment and outcomes of prostate disease in Denmark to those reported by the Dartmouth and Maine group from the U.S. This will allow us to examine a number of significant features of medical practice that studies of the U.S. population alone do not permit. (P.I. Andersen)

It was from our broad perspective in looking at the cost and quality of patient care that a number of our projects have come together to establish a direction for the Patient Outcome Assessment Research Program.

In particular, NCHSR has supported a great many studies of resource allocation in the health care system, including those which contributed to the development of the DRG system. We initiated the development of small area variation Analysis. Many of our grants have concentrated on developing ways to measure severity of illness and patient outcome, methods which remain the current standards.

One of our first efforts was to complete the National Halothane Study, and to follow with the Institutional Differences Study, demonstrating clearly that medical practices vary within hospitals, between hospitals and among regions, and that these variations can result in significant differences in patient outcomes. We have developed the field of health services research and have applied cost benefit and cost effectiveness analyses to treatments and their outcomes. We pioneered in studies of group and individual medical decision making. NCHSR has fostered the study and development of mechanisms of feedback and computer assisted clinical decision making to discover the most efficient ways to change provider behavior.

Never before have the results of our efforts been so apparent in one major program. Our enthusiasm for POARP and the wide support it is receiving arises from the fact that POARP is not only desirable, but also, timely and practical. It is desirable because it will improve quality, reduce uncertainty, and conserve resources. It is timely and practical because data bases to identify the problems, and the computers and software necessary to analyze the data exist. The methods, developed in large part with NCHSR support, are available for doing comparative studies, for synthesizing literature, for measuring severity of illness, quality of care and individual health status. Scientists versed in the necessary disciplines required for health services research of this type are out there in some number because of the support of these prior efforts (e.g., decision analysts, clinical epidemiologist, health economists, etc.).

The time is right for doing patient outcome research. All the pieces are in place. What we need to focus on now is what we want to study and how best to do it.

NCHSR has maintained a strong reputation for relevant and valid scientific work, established by our authorizing legislation which guarantees peer review and by our own diligent efforts to encourage both investigators and peer reviewers to be independent thinkers. Because of this we can provide a linkage for all the involved parties.

In cooperation with other agencies, including HCFA, and in consultation with members of the practicing and research communities, NCHSR has drafted criteria for the selection of conditions to be studied. These include:

1. Differences among alternative treatments or settings with regard to:
    a. Health benefits
    b. Risks to the patients
    c. Costs to the population

2. Frequency and distribution in the population

3. Availability of appropriate data

4. Amount of unexplained variation

These criteria are being applied to applications for research funds in POARP and will be in the broader National Program for the Assessment of Patient Outcomes (NPAPO) which NCHSR has proposed. Both programs would use the same model to study health care uncertainties. But NPAPO concentrates on issues for which the use of Medicare funds might not be appropriate (for example, the treatment of younger patients). This could include conditions and procedures like hysterectomy, Caesarian delivery, otitis media, dental implants and some procedures which, though used on patients of all ages, might have different utilities dependent on age.

Our approach to the research includes the following activities:

1. Multi-disciplinary Assessment teams which include practicing physicians,
2. Other investigator-initiated assessments,
3. Experimental trials as required,
4. Data source development and maintenance,
5. Training of research manpower, and
6. Demonstrations of the effectiveness of the research products.

As research is completed under POARP, the results will be widely disseminated and, also, transferred to our sister agency in the PHS, the Health Resource and Services Administration, for them to assure the findings become integrated into medical education. It is anticipated that this base of knowledge about patient outcomes will be useful to practicing physicians, HCFA, PROPAC, and PHYPRC for carrying out their responsibilities and that private third party payors could utilize these results as well, all serving to provide the highest quality of care in a cost effective manner.

I share the Secretary's enthusiasm for patient outcome research and look forward to continuing our research efforts and to sharing the results of our studies with you as they become available.

OPENING STATEMENT
SENATOR JOHN HEINZ

SENATE FINANCE HEALTH SUBCOMMITTEE ON HEALTH
HEARING ON PATIENT OUTCOME ASSESSMENT RESEARCH
JULY 11, 1988

MR. CHAIRMAN:

WHEN CONGRESS TOOK THE BIG STEP TO CONTROL MEDICARE COSTS IN 1983 WITH A SHIFT TO PROSPECTIVE PAYMENT, IT CREATED INCENTIVES FOR HOSPITALS TO MINIMIZE PATIENT CARE. AT THAT TIME, I WAS CONCERNED THAT WE HAD NO WAY OF KNOWING WHAT WAS HAPPENING TO PATIENTS AS A RESULT. HEARINGS I CHAIRED BEFORE THE SENATE AGING COMMITTEE IN 1985 AND 1986 REVEALED ANECDOTAL EVIDENCE THAT HOSPITALS WERE RESPONDING TO PROSPECTIVE PAYMENT BY DISCHARGING PATIENTS "SICKER AND QUICKER". HOWEVER, BECAUSE WE WERE JUST BEGINNING TO MONITOR PATIENT CARE AND ASSESS PATIENT OUTCOMES AT THAT TIME, THERE WAS NO SOLID EVIDENCE ONE WAY OR THE OTHER.

MUCH HAS BEEN DONE IN THE LAST FEW YEARS TO CORRECT THIS DEFICIENCY. THE PEER REVIEW ORGANIZATIONS CREATED BY CONGRESS HAVE DONE MORE TO MONITOR THE QUALITY OF CARE BASED ON QUALITY STANDARDS AND REVIEW AND ENFORCEMENT REQUIREMENTS. THE ADMINISTRATION HAS BEEN RESEARCHING NEW MEASURES OF QUALITY AND DEVELOPING DATA TO ASSESS THE QUALITY OF CARE.

ONE OF THE FIRST PRODUCTS OF THIS EFFORT HAS BEEN THE ADMINISTRATION'S ANNUAL RELEASE OF HOSPITAL MORTALITY STATISTICS. I BELIEVE THESE DATA HAVE MADE AN IMPORTANT CONTRIBUTION BY FOCUSING PUBLIC ATTENTION ON THE

EFFECTIVENESS OF INDIVIDUAL HOSPITALS AND BY EMPHASIZING THE NEED FOR CONSUMER AWARENESS OF HOSPITAL QUALITY. BUT THE MORTALITY DATA ARE NOT YET A VALID MEASURE OF QUALITY - AS REPORTS I RELEASED THIS MORNING BY GAO AND THE NEW YORK STATE DEPARTMENT OF HEALTH CONFIRM. IN ADDITION, MORTALITY IS NOT THE ONLY PATIENT OUTCOME WE NEED TO MEASURE. MOST PATIENTS IN HOSPITALS DO NOT DIE, AND WE NEED TO KNOW ABOUT THEIR OUTCOMES AS WELL TO KNOW HOW GOOD A HOSPITAL IS. WITH THE CHAIRMAN'S PERMISSION, I WOULD LIKE TO SUBMIT SUMMARIES OF THE GAO AND NEW YORK REPORTS FOR THE RECORD.

MORE IMPORTANTLY, WE NEED TO LOOK BEYOND HOSPITAL SETTINGS IN EVALUATING PATIENT CARE. COST CONTAINMENT PRESSURES ARE FORCING CHANGES IN MEDICAL PRACTICE IN ALL TYPES OF SETTINGS IN WAYS THAT CAN AFFECT BOTH THE UTILIZATION AND THE QUALITY OF CARE. WE NEED TO KNOW WHAT IS EFFECTIVE AND NECESSARY CARE IN NURSING HOMES, AMBULATORY CARE SETTINGS, HOME CARE, AND OTHER SETTINGS.

IN THE LAST FEW YEARS, THE ADMINISTRATION HAS MADE PROGRESS IN MOVING OUR QUALITY AGENDA FORWARD. IN ADDITION TO THE HOSPITAL MORTALITY DATA, THE ADMINISTRATION WILL SOON RELEASE DATA TO THE PUBLIC ON NURSING HOME PERFORMANCE. MORE IMPORTANTLY, THEY HAVE BEGUN TO ENCOURAGE RESEARCH AND DEVELOPMENT OF MEASURES OF PATIENT OUTCOME THAT CAN BEGIN TO ANSWER THE QUESTIONS WE POSED FIVE YEARS AGO.

I WILL BE INTERESTED IN LEARNING TODAY WHAT THE TIMEFRAME IS FOR DEVELOPING DATA ON PATIENT OUTCOMES NOT JUST IN HOSPITAL SETTINGS, BUT IN OTHER SETTINGS AS WELL; AND HOW WE WILL USE THESE DATA TO IMPROVE PHYSICIAN PRACTICES AND MONITOR THE EFFECTIVENESS AND QUALITY OF PATIENT CARE. I WILL ALSO BE INTERESTED IN KNOWING WHAT ROLE THE HOSPITAL MORTALITY DATA WILL PLAY AND HOW THE ADMINISTRATION PLANS TO IMPROVE THE DATA BEFORE IT IS RELEASED AGAIN.

MR. CHAIRMAN, I COMMEND YOU FOR YOUR LEADERSHIP IN THE AREA OF QUALITY GENERALLY. THE LEGISLATION YOU HAVE INTRODUCED TO INCREASE FUNDING FOR PATIENT OUTCOME RESEARCH IS PARTICULARLY TIMELY AND IMPORTANT, AND I AM PLEASED TO BE A CO-SPONSOR. I THANK YOU FOR CONVENING TODAY'S HEARING.

United States General Accounting Office

GAO

Report to the Ranking Minority Member,
Special Committee on Aging, U.S. Senate

June 1988

MEDICARE

Improved Patient Outcome Analyses Could Enhance Quality Assessment

GAO/PEMD-88-23

GAO **United States**
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-229397

June 27, 1988

The Honorable John Heinz
Ranking Minority Member
Special Committee on Aging
United States Senate

Dear Senator Heinz:

This report responds to your November 4, 1986, letter asking us to examine the Health Care Financing Administration's (HCFA) analysis and use of existing administrative data to monitor patient outcomes under the Medicare program. As you requested, we compared the approaches that HCFA has employed in its internal analyses of Medicare outcomes to analogous approaches developed by HCFA contractors and independent researchers. We also examined the feasibility of using Medicare administrative data to assess the effects of the prospective payment system (PPS) on patient outcomes.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of the report. We will then send copies to interested congressional committees, the Secretary of Health and Human Services, the Administrator of HCFA, and other interested parties, and will make copies available to other persons upon request.

Sincerely yours,

Eleanor Chelimsky,
Director

Executive Summary

Purpose

In March 1986 and again in December 1987, the Health Care Financing Administration (HCFA) identified specific hospitals having mortality rates that were substantially higher or lower than expected given the mix of Medicare patients they treated. These analyses attracted widespread interest as well as concerns about misinterpreting the results.

At the request of the ranking minority member of the Senate Special Committee on Aging, GAO examined HCFA's approach to analyzing Medicare patient outcomes. The primary question was whether HCFA could obtain more or better information to guide Medicare quality assurance activities using the administrative data on individual patients that it already collects. The five study objectives were to (1) describe the approaches HCFA employs to analyze existing Medicare administrative data on mortality and morbidity as an indicator of the quality of hospital care, (2) examine the uses that HCFA has made of these outcome analyses to guide quality assurance in the Medicare program, (3) identify other relevant approaches that could be applied to Medicare administrative data, (4) assess the relative strengths and limitations of HCFA's and other approaches in terms of their substantive focus and technical quality, and (5) determine the feasibility of analyzing administrative data to assess changes in Medicare patient outcomes associated with the introduction of the prospective payment system in 1983.

Background

Primary responsibility for ensuring quality care for Medicare hospital patients rests with the 54 state-level Peer Review Organizations (PROs). They fulfill this function through reviews of medical records by nurses and physicians for selected cases. Patient outcome analyses based on Medicare's administrative data files provide a useful complement to the PRO reviews because the uniform billing data on every Medicare patient permits an efficient and consistent examination of all cases.

One difficulty confronting outcome analyses based on administrative data files is the restricted range of clinical data generally included in such files. Analysts need clinical data to adjust for differences among patients in "severity of illness"; that is, their intrinsic risk of dying or experiencing other adverse outcomes, independent of the quality of care received. With adequate adjustments, typically based on differences in diagnosis and general health status, comparisons of health care outcomes may provide a credible indication of quality of care.

Results in Brief

A comparison of the 1986 and 1987 hospital mortality analyses shows that HCFA has strengthened the technical quality of its analyses. However, it could make additional improvements in the key area of patient severity adjustment. To make future analyses of Medicare patient outcomes more credible and useful, HCFA should more fully validate the analytical approaches selected, systematically check its data for accuracy and completeness, and analyze outcomes from several years to reduce the effect of random variation. HCFA's application of Medicare patient outcome analyses has so far been limited, and not notably effective in identifying quality problems.

Principal Findings

The 1987 hospital mortality analyses improve on the 1986 analyses in their use of patient-level data, clinically coherent diagnostic groups, information on comorbidities, and more appropriate techniques to adjust for severity of illness. HCFA also maintains ongoing monitoring systems that compare outcomes over time and across a limited number of patient subgroups.

HCFA's major use of its outcome analyses was to require organizations bidding to remain or become PROs in 1986 to examine the hospitals identified in HCFA's 1986 analyses. GAO found that the PROs confirmed only a handful of these hospitals as having definite or likely quality problems. The data cannot answer why this occurred, but GAO believes that a careful investigation of this issue should precede any future use of similar outcome analyses to target PRO reviews.

GAO identified six distinct approaches to analyzing Medicare patient outcome data, in addition to the three employed by HCFA. Four emerged from HCFA's extramural research program, and two were developed independently.

GAO found that several of the approaches developed independently or by HCFA contractors adjusted for differences in patient severity in ways that took greater advantage of the clinical data on principal diagnoses and procedures available in administrative files than did HCFA's approaches. HCFA could potentially achieve similar results by incorporating comparable risk variables into future mortality analyses.

Several approaches that analyze patient subgroups demonstrate the potential for identifying types of cases with unusually favorable or adverse outcomes. HCFA has primarily compared mortality rates among individual hospitals. If HCFA were to expand its analyses of patient subgroups, rather than hospitals, using more sophisticated adjustments for patient severity, it could then test whether outcome analyses focusing on patient subgroups defined by demographic or diagnostic characteristics would usefully supplement, or partially substitute for, hospital-based analyses as a way of targeting PRO quality reviews.

Certain limitations apply to all nine analytical approaches. First, none has yet been adequately validated for effectiveness in targeting cases for quality review. Adequate testing would involve systematic comparison of outcomes using these approaches to outcomes derived from a detailed review of medical records or other available evidence of quality of care. Second, all of the approaches are vulnerable to missing and inaccurate data in Medicare's administrative files. Until HCFA establishes the nature and magnitude of such problems for each data element used by these approaches, the effect of such deficiencies on analyses of Medicare patient outcomes will remain unknown.

Third, all the approaches must contend with the uncertainty that random variation introduces to analyses of mortality rates, especially those that involve small numbers of cases. In its 1987 hospital analyses, HCFA took account of random variation by calculating a range of expected mortality for each hospital. The breadth of these ranges increased as the number of cases analyzed declined; thus observed mortality for smaller hospitals had to deviate more markedly from expected mortality to fall outside the predicted range. This made the HCFA analysis less capable of detecting relatively poor outcomes for smaller hospitals. One solution would be to combine Medicare patient data from several years. Hospitals with larger numbers of Medicare patients could still be analyzed yearly to monitor short-term trends in outcomes.

Finally, existing analytical approaches using Medicare administrative files provide little capability for analyzing outcomes other than mortality. HCFA has addressed this problem in its most recent extramural grant solicitation.

An analysis of changes in Medicare patient outcomes associated with the shift to prospective payment could be conducted using existing administrative files. However, the results would be open to challenge, owing to the likelihood of major systematic error in the diagnostic information needed to adjust for patient severity, as well as the difficulty of distinguishing PPS-induced changes from other changes likely to have occurred over the lengthy period of phasing in prospective payment.

Two ongoing HCFA studies may produce much of the information about the effects of PPS that is feasible to derive, given the limitations of the available data.

Recommendations to the Secretary of HHS

GAO recommends that the Secretary of HHS direct the Administrator of HCFA to (1) strengthen HCFA's outcome analyses by adopting specific improvements identified in this report, such as taking greater advantage of available diagnostic data in adjusting for patient severity of illness, employing data for several years when analyzing outcomes involving small numbers of cases, and expanding HCFA's analysis of comparative outcomes among demographic and diagnostic subgroups of patients (see pp. 96, 97, and 99); and (2) improve outcome analyses more generally by actions outlined in this report, such as periodically assessing the relative strengths and limitations of available approaches for analyzing Medicare patient outcome data in terms of substantive focus, technical adequacy, and degree of validation (that is, their overall effectiveness in identifying patterns of patient care with quality problems). Further, HCFA should evaluate the completeness and accuracy of the data elements that are used to analyze Medicare patient outcomes. The assessment should be based on a nationally representative sample of Medicare patients. The results should be published and appropriate corrective actions taken. (See pp. 102 and 103.)

Agency Comments

While HHS found the report "thorough and scholarly" and generally concurred with GAO's recommendations, its comments do not always address the specific points raised in those recommendations. For example, the Department described its longer term efforts to expand the clinical data in its administrative files, but did not comment on GAO's proposals to strengthen patient severity adjustment in HCFA's interim analyses using its existing data sets. Overall, the GAO recommendations would both strengthen HCFA's analyses in the near term and facilitate more fundamental improvements by establishing procedures for validating analytical approaches and assessing data accuracy. HHS' comments pertaining to the recommendations and GAO's responses are presented in chapter 6; technical comments are addressed in appendix II.

United States General Accounting Office

GAO

Report to the Ranking Minority Member,
Special Committee on Aging, U.S. Senate

June 1988

VA HOSPITAL CARE

A Comparison of VA and HCFA Methods for Analyzing Patient Outcomes

GAO/PEMD-88-29

GAO

United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-229397.3

June 30, 1988

The Honorable John Heinz
Ranking Minority Member
Special Committee on Aging
United States Senate

Dear Senator Heinz:

In response to the request made by your office, we have examined the methodology developed by the Veterans Administration (VA) to analyze mortality rates in its hospitals and compared it to the approach recently used by the Health Care Financing Administration (HCFA) in analyzing the mortality rates of hospitals treating Medicare patients.

Results in Brief

We found that the Veterans Administration modeled its approach to analyzing hospital mortality data after that employed by HCFA in its 1987 analyses of Medicare hospitals. Thus both analyses are broadly similar. To accommodate the particular characteristics of its hospital patients, VA made some changes, such as modifications in the diagnostic categories analyzed. Other refinements it made to HCFA's approach would apply equally well to Medicare analyses. Some of the improvements parallel conclusions and recommendations we made in a separate report that examines HCFA's analyses of Medicare patient outcomes, notably its statistical adjustment for the mortality risk associated with specific primary diagnoses.[1] However, VA also adjusted for two other variables, race and total length of hospital stay, which under certain circumstances could mask some differences in quality of care across hospitals. The Veterans Administration deserves credit for planning validation efforts in conjunction with the initial development of its approach; HCFA has recently begun to direct its attention to validation as well.

Background

Mortality analyses based on computerized data in hospital discharge abstracts provide a means for efficiently screening large numbers of cases in order to focus more intensive review efforts on those hospitals that are most likely to have quality of care problems. The accuracy of these analyses for screening purposes depends in part on how well they use the limited data on patient characteristics from administrative data files to adjust observed differences in outcomes among hospitals for variations in the relative condition of their patients at admission. These adjustments are intended to take account of the increased mortality experienced by more severely ill patients, independent of the quality of care they receive.

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[1] U.S. General Accounting Office, Medicare: Improved Patient Outcome Analyses Could Enhance Quality Assessment, GAO/PEMD-88-23 (Washington, D.C.: June 1988), p. 96.

HCFA released its first mortality analyses encompassing all Medicare hospitals in March 1986, and issued a second set based on a substantially revised methodology in December 1987.[2] VA published its plans to conduct similar analyses of its own hospitals in February 1988.[3]

Objectives, Scope, and Methodology

As requested, our objective was to compare the analytical approach used in the VA's ongoing hospital mortality analyses to that employed in HCFA's 1987 analyses.

We based our analysis of the VA's approach on the circular cited above that formally established its policy for conducting mortality rate analyses and on interviews with the Acting Director and staff of its Office of Quality Assurance. Because the analyses had not been completed at the time this report was prepared, we did not have the opportunity to review the results for individual hospitals. Nor did we independently check the accuracy of the data files that VA employed. We discussed our observations on the approach with officials in the Office of Quality Assurance and incorporated suggested changes where appropriate. However, as requested by your office, we did not obtain written agency comments.

Our description of HCFA's analyses summarizes material presented in our Medicare report cited above along with updated information on HCFA's plans to validate its approach. HCFA had previously commented on a draft of that report.

We performed our review in accordance with generally accepted auditing standards.

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[2] Health Care Financing Administration, Medicare Hospital Mortality Information: 1986, HCFA Pub. No. 01-002, 7 vols. (Washington, D.C.: U.S. Government Printing Office, 1987).

[3] Veterans Administration, "FY 1986 Patient Treatment File Mortality Analysis," Circular 10-88-17 (Washington, D.C.: Feb. 16, 1988).

Comparison of the Two Approaches

The Veterans Administration took the HCFA approach as its point of departure, thus the two analyses have many similarities. Both produce information about the outcome of care provided in specific hospitals by examining the mortality rate of patients treated in those hospitals. Both also attempt to make the assessment of hospital mortality more accurate by comparing each hospital's observed mortality to an expected mortality rate that adjusts statistically for variation among hospitals in patient severity or condition, that is, the characteristics of their patients that are likely to affect the probability of death.[a] However, the two approaches differ somewhat in the way they measure mortality, in the factors they consider to adjust for patient severity, in their methods for assessing the difference between observed and expected mortality, and in the current plans of the two agencies for systematic validation of their results.

In addition, HCFA and VA differ in the intended use of their analyses. HCFA designed its analyses specifically to provide information to the public about the relative performance of individual hospitals. It hoped that the publicized results would lead medical and administrative staff, as well as patients, to raise questions about hospitals whose observed mortality substantially exceeded that for other hospitals with a comparable mix of patients. The Veterans Administration, by contrast, planned to use its hospital mortality analyses primarily to guide its own internal quality assurance activities. Nevertheless, VA recognized that it might have to share the results if someone outside the agency requested them, and in any case plans to publicly release them by the end of 1988.[b]

Measuring Mortality

HCFA and VA both calculate mortality for nonsurgical patients as any death that occurs within 30 days of a hospital admission (or transfer to an acute care section in a VA hospital), regardless of when the patient is discharged from the hospital. For surgical patients, VA counts 30 days from the date of the procedure; HCFA, from hospital admission.

HCFA obtained information on dates of deaths both before and after hospital discharge from Social Security files. VA drew on its own hospital discharge abstract file, the Patient Treatment File, for information on inpatient deaths. It relied on its Beneficiary Identification and Record Locator Sub-system for data on postdischarge deaths. Because the latter file has information on some, but not all, veterans treated in VA hospitals, the VA analysis underestimated postdischarge mortality by an unknown amount.

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[a] We use the terms "patient severity" or "patient condition" to refer to a wide range of demographic (e.g., age and sex) and clinical factors, including both principal diagnosis (the main reason for admission to a hospital) and comorbidities (diagnosed problems that are not related to the principal diagnosis), that could affect a patient's prospects for recovery.

[b] VA is currently considering a Freedom of Information Act request for the results of its hospital analyses.

For patients with multiple hospital admissions, both HCFA and VA analyze only the results of the last full hospital episode in the year. In our report on Medicare patient outcome analyses cited above, we criticize HCFA's decision not to examine the outcome of all hospital episodes. The purpose of both the HCFA and VA analyses was to assess the performance of individual hospitals, several of which may have cared for a given patient at different times in the year. By ignoring the outcome of earlier hospital episodes, both HCFA and VA excluded information relevant to these assessments. If some hospitals tended to provide a substantially higher proportion of the excluded hospital episodes than others, the restriction of the analysis to each patient's last hospital discharge would increase their observed mortality rates more than for other hospitals.[6]

Adjustment for Patient Severity

HCFA and VA both apply a statistical technique called logistic regression to adjust for differences in patient severity across hospitals. Both analyze separately the mortality of patients belonging to broad diagnostic categories, and both employ the results of these regression analyses to determine the relationship of various patient characteristics to the risk of mortality within these groups. Each then uses the coefficients produced by these equations to calculate the probability of death for each patient. Summing across patients treated in a given hospital generates an estimate of that hospital's predicted or expected death rate. This provides a standard against which to compare the hospital's actual or observed death rate that takes into account variations in the condition of patients that different hospitals admit for treatment. (Appendix I describes these procedures in greater detail.)

The adjustments for patient severity in the HCFA and VA approaches differ primarily in the way patients are divided into groups for separate regression analyses and in the patient risk factors they consider.

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[6] Since all the patients in the excluded hospital episodes survived, their inclusion in the analysis would lower the observed mortality rate for the hospitals that treated them.

Patient Groups

HCFA developed 17 diagnostic categories based on a patient's "principal" diagnosis, which is defined as the main reason for admission to the hospital, determined after examining the entire medical record. VA does not record principal diagnoses in its Patient Treatment File; instead it identifies each patient's "primary" diagnosis, which represents the illness or condition accounting for most of the days spent in the hospital. Therefore, VA developed 14 diagnostic categories based on primary diagnoses. For purposes of adjusting for patient condition at admission, principal diagnoses are in our view preferable to primary diagnoses, since the latter may sometimes represent complications that occur following admission as a consequence of the treatment provided.

VA began with the 16 specific diagnostic categories devised for the HCFA analysis, but found that a higher proportion of VA than Medicare patients fell into the 17th residual category for "all other conditions." VA analysts therefore modified the HCFA categories, so that less than 20 percent of cases remained in the residual category. Appendix II compares the 17 HCFA and 14 VA diagnostic groups.

The VA analyses also divide patients into four groups according to whether a procedure was performed, and if so, what type. The groups consist of patients who received (1) no procedures at all, (2) surgical procedures, (3) operative diagnostic and palliative procedures (e.g., biopsy, tracheostomy), and (4) nonoperative procedures (e.g., CAT scan). However, the VA data files did not contain information that would allow analysts to distinguish between elective and nonelective surgery, a major risk indicator for surgical cases.[7]

VA conducted a separate regression analysis for patients in each of the 14 diagnostic clusters (including the residual group) within each of the four patient groups. However, VA consolidated some diagnostic categories because the number of patients within them were very small. These consolidations led to a total of 27 regression equations.

Risk Factors

Table 1 compares the risk factors that HCFA and VA entered into their regression analyses. The Veterans Administration included in its regression equations all the factors that HCFA considered and added four more: race, total length of hospital stay, the VA system-wide mortality rate for specific primary diagnoses, and the total number of additional diagnoses

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[7] See Mark S. Blumberg, "Measuring Surgical Quality in Maryland: A Model," Health Affairs, vol. 7, no. 1 (Spring 1988), p. 64.

(beyond the primary). It also changed HCFA's variable on transfers from other acute care hospitals to reflect instead transfers from VA nursing homes and altered the way in which it calculated previous hospitalizations.

Table 1: Risk Factors Included in Regression Analyses to Predict Patient Mortality

Health Care Financing Administration	Veterans Administration
Age	Age
Sex	Sex
	Race
Prior Medicare hospitalizations (within calendar year)	Prior VA hospitalizations (within previous 12 months)
Transfers from other Medicare acute care hospitals	Transfers from VA nursing homes
8 Comorbidities	12 Complicating conditions[a]
	Total number of additional diagnoses (beyond primary)
	Total length of hospital stay
	System-wide mortality rate for individual primary diagnosis

[a] VA included in any given regression equation those complicating conditions that a preliminary analysis showed were significantly related to mortality for the particular patient group being analyzed

VA adjusted for seven of HCFA's eight comorbidities or chronic conditions, in whole or in part, and added five others.[8] For each of its 27 regression equations, VA analysts included those chronic conditions that preliminary statistical analyses showed were significantly related to increased mortality in that group of patients. They also considered HCFA's eighth comorbidity, hypertension, but found that it was not associated with higher mortality for any of the patient groups analyzed. Appendix III compares the two lists of chronic conditions.

We have some reservations about two of the factors that VA added—race and total length of hospital stay. However, we find that its introduction of a third new variable for system-wide primary diagnosis mortality rate and its modification of the prior hospitalization variable represent a clear improvement over HCFA's approach. Our discussion of these factors follows.

Race. Our report on HCFA's analyses of Medicare patient outcomes discusses the issues raised by statistical adjustment for race (GAO/

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[8] VA calls these "complicating conditions," but describes them as "chronic underlying ailments," which suggests that their purpose was to adjust for conditions that existed prior to the patient's admission for acute care, and not for complications of treatment that developed after admission.

PEMD-88-23, p. 22). To the extent that differences in outcomes associated with race derive from physiological differences that influence the probability of death, then such statistical adjustments are appropriate. However, the adjustments that VA made for race would simultaneously mask any differences in outcomes that reflect systematic variations in the quality of care received by patients of different races. Without knowing the relative influence of physiological characteristics and discriminatory practices on racial variation in patient outcomes, we cannot determine the appropriateness of an adjustment for race.

Total length of hospital stay. The VA's adjustment for total length of hospital stay raises somewhat similar concerns. It added this variable to its regression analyses to identify patients who had been receiving long-term care before being transferred to an acute care section of the same facility.[9] However, this variable does not differentiate between the length of time spent in the hospital prior to admission to the acute care section and the number of days spent in acute care. Relatively lengthy acute care could reflect a greater severity of illness at admission, but it could also result from complications of treatment, such as nosocomial infections, that reflect poor quality care. Generally speaking, adjustment variables that relate directly to patient characteristics are less prone to this type of ambiguity than variables such as length of stay that describe the nature of the treatment provided.

System-wide primary diagnosis mortality rate. Both HCFA and VA structure their analyses around a limited number of quite broad diagnostic categories. HCFA relies on these diagnostic categories to adjust for differences across hospitals in case-mix, that is, the distribution of principal diagnoses among patients. However, since these broad categories encompass individual diagnoses that vary substantially in overall death rates, relying on these categories alone can advantage some hospitals in the analysis and disadvantage others, depending on the proportion of patients that they admit with high-risk and low-risk diagnoses within a given diagnostic category.

VA has addressed this problem by entering an additional risk factor into each of its regression equations that reflects the specific probability of death associated with a given individual primary diagnosis across the VA system as a whole. VA analysts found that this variable was highly significant statistically in all 27 regression equations, which means that its inclusion consistently made an appreciable difference for the predicted mortality of individual patients. By adjusting for the variation in risk among primary diagnoses, VA made its analyses less prone than HCFA's to either an overestimation or underestimation of the expected mortality rate of hospitals as a result of differences in their case-mix within diagnostic categories.

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[9] VA hospitals provide relatively large amounts of long-term as well as acute care. Patients shifted from psychiatric or nursing beds to acute care beds within the same hospital would not be identified by the variable on transfers, which reflects transfers from VA nursing homes.

Prior hospitalizations. VA also improved on HCFA's variable for prior hospitalizations by consistently counting all discharges in the 12 months preceding the patient's last hospital episode. HCFA, by contrast, only took account of prior hospital episodes during the same calendar year. This means that the time period within which HCFA counted prior hospitalizations varied substantially among patients, depending on when their last hospital discharge occurred in the year.

Assessing Observed Versus Expected Mortality

Both the HCFA and VA analyses assess the outcomes of individual hospitals by comparing their actual observed mortality rate to an expected mortality rate generated from the results of the regression analyses. The discrepancy between the expected and observed mortality rates indicates how much better or worse the outcomes of patients are at specific hospitals compared to outcomes of similar patients treated at other hospitals. For a number of reasons, the "true" discrepancy between observed and expected mortality for a given hospital may be greater or less than that indicated by the HCFA or VA analyses. Therefore, both approaches employ statistical techniques for identifying hospitals where it is most likely that observed and expected mortality rates are in fact substantially different.

The HCFA analyses accomplish this through a formula that converts the specific estimate of predicted mortality for each hospital into a range intended to encompass that hospital's "true" predicted mortality with a 95-percent certainty. Depending primarily on the number of patients treated by that hospital, the range can be quite narrow or large. Thus, the formula takes into account the greater uncertainty brought about by chance variation in a hospital's observed mortality rate, either overall or for a given diagnostic category, if that rate derives from a relatively small number of cases.

In addition, the HCFA formula for generating predicted mortality rates contains an "interhospital variance" term, which takes into account nonrandom, that is systematic, differences across hospitals that are related to their outcomes but not specified in HCFA's regression equations. These include differences in patient severity that HCFA's regression analyses may not have captured. They also include variations in the quality of care provided by different hospitals. Thus, hospitals whose observed mortality exceeds their range of predicted mortality differ from the predicted by a margin that is substantially larger than would be expected given typical differences among hospitals as well as random fluctuations from year to year.

VA employs a quite different approach. First, it computes the ratio of observed-to-expected mortality for each hospital. It then calculates an upper and lower limit for this ratio, using a formula frequently employed by epidemiologists to compute standardized mortality ratios. This formula takes account of chance variation in observed hospital mortality, but not systematic variation. If the range between the upper and lower limit does not include 1.0 (which would indicate that expected mortality equaled observed mortality), then the difference between expected and observed mortality is considered statistically significant at the 95-percent confidence level.[10]

Until both the HCFA and VA analytical approaches have been tested, we cannot determine which method for setting confidence intervals discriminates more accurately between hospitals providing good and poor quality care. HCFA's formula for calculating a range of predicted mortality, which takes systematic differences among hospitals as well as random fluctuation into account, might prove advantageous if most of the systematic differences in outcomes reflect variations among hospitals in patient severity that were not accounted for in its regression equations. However, if most of the systematic differences reflect variations in quality of care, the HCFA formula would undermine effective screening of problem hospitals. The VA's confidence intervals have the advantage of being relatively simple and less novel than HCFA's, employing a well-known formula that many researchers recognize and understand.

Validation

Validation refers to a systematic assessment of the overall effectiveness of an approach in accurately locating quality of care problems. Full-scale validation requires evidence drawn from independent sources of information that are separate from the data files used for the original analyses. Medical record reviews of a sample of cases is one, though by no means the only, source for validating evidence. At this point neither VA nor HCFA has validated the approaches employed in their hospital mortality analyses, although both are developing plans to begin this process.

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[10] In other words, the probability that hospitals would have "true" ratios of observed-to-expected mortality that fall outside this range as a result of random variation is less than 5 out of 100.

HCFA published its analyses of hospital mortality rates in December 1987 without any validation of the results based on independent sources of information. However, HCFA is currently planning two validation efforts for the next round of hospital analyses scheduled for release at the end of 1988. One will compare hospital outcomes in the mortality analysis to the results of generic screen reviews conducted by Peer Review Organizations (PROS).[11] The other will involve abstracting clinical information from cases treated in a sample of hospitals to see what effect a more rigorous adjustment for patient severity would have on the results of the hospital mortality analyses.

The Veterans Administration also has two validation efforts under consideration. In one, its own peer review organizations (MEDIPROS) would conduct intensified reviews of the hospitals identified as having higher-than-expected mortality rates. VA had not yet determined how these reviews would be performed and made comparable across the different MEDIPROS when we concluded our data collection. The second effort, proposed by analysts in the VA's Office of Research and Development, would provide a more systematic validation of the VA's approach. It would examine cases from hospitals that the mortality analyses had rated as having low, medium, and high death rates. In addition, a single panel of physicians applying a standard set of criteria would review all cases. This effort, depending on whether VA decides to pursue it and what specific form it takes, could provide more comprehensive validating information than either of the two studies HCFA plans to perform.

We plan no further distribution of this report for 30 days. At that time we will send copies to the Secretary of Health and Human Services, the Administrators of HCFA and VA, and to other interested congressional committees. We will also make copies available to interested parties on request.

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[11] The generic screens, which the PROs have applied since 1986 to all cases that they review, require reviewers to examine the medical record for indications of six specific types of adverse events. These include premature discharges, unexpected deaths, nosocomial infections, and drug reactions or medication errors.

If you have any questions, please call me at (202) 275-1854 or Lois-ellin Datta at (202) 275-1370.

Sincerely yours,

Eleanor Chelimsky
Director

HCFA and VA Statistical Methodologies for Calculating Expected Mortality

1. Patients are divided into groups; 17 diagnostic clusters for HCFA, 27 groups defined by procedure and diagnostic category for the Veterans Administration.

2. For each patient group, a separate logistic regression equation is estimated, including the independent variables listed in table 1. The dependent variable is individual patient mortality, coded dichotomously as alive or dead 30 days after admission, or after the procedure for the VA analysis. The independent variables are the same within the HCFA and VA analyses for each patient group, except that in the VA analysis only those chronic conditions that proved in preliminary crosstabulations to be significantly associated with higher mortality for that patient group are included in the equation.

3. For each patient group analyzed, the regression equations generate coefficients for each of the independent variables. These measure the association of that particular risk factor with patient mortality, controlling for the effects of the other factors in the equation. Applying these coefficients to the characteristics of each individual patient (age, sex, diagnoses, and so forth) permits analysts to compute the probability of death for that specific patient.

4. The expected mortality of a hospital, either overall or for specific patient groups, is calculated as the sum of the individual probabilities of death for all patients in that group. For example, if a hospital treated three patients, with probabilities of death of 0.3, 0.5, and 0.4, the number of expected deaths would be 1.2. Dividing that figure by the number of patients treated produces an expected mortality rate, in this case 0.4.

Appendix II

Comparison of HCFA and VA Diagnostic Categories

Risk group	Health Care Financing Administration		Veterans Administration	
	Diagnostic category	**ICD-9-CM codes**	**Diagnostic category**	**ICD-9-CM codes**
High	Cancer	141-160, 162-172, 174-209	Cancer	141-160, 162-172, 174-209
	Stroke	430-432, 434, 436	Cerebrovascular disease	430-438
	Severe acute heart disease	410, 427.1, 427.4, 427.5, 441.0, 441.1, 441.3, 441.5, 441.9, 785.51	Severe heart disease	398.91, 402.01, 402.11, 402.91, 410, 425, 427.1, 427.4, 427.5, 428, 441.0, 441.1, 441.3, 441.5, 441.9, 518.4, 785.51
	Severe chronic heart disease	398.91, 402.01, 402.11, 402.91, 425, 428, 518.4		
	Gastrointestinal catastrophes	551, 557, 560.0, 560.2-560.9, 570, 572-572.7, 573.4, 567, 578.0, 578.9	(See gastrointestinal disease below)	
	Metabolic and electrolyte disorders	250.01-250.4, 251.0, 251.1, 255.4, 276	Metabolic and electrolyte disorders	250, 251.0, 251.1, 255.4, 276
	Pulmonary disease	415.1, 416.0, 480-483, 485-516, 518-519, except 516.1 and 518.4	Pulmonary disease	415.1, 416.0, 480-483, 485-516, 518-519, except 516.1 and 518.4
	Renal disease	580-590 except 580.81 and 590.81	(See renal and urologic disease below)	
	Sepsis	31, 202, 223, 362, 363, 368.9, 369, 380, 381, 382, 383, 384.0-384.4, 384.9, 388, 389, 545, 790.7	(See infectious and parasitic disease below)	
	Severe trauma	806, 808.43, 808.53, 820, 821, 828, 850.2, 850.4, 851.1-851.7, 852, 839.0-839.5, 860-867, 887, 897, 900.0, 901-904, 926, 927.0, 928.0, 929.0, 942.3, 942.4, 942.5, 946.3-946.9, 947.1-947.9, 948.2-948.9, 952, 958.0, 958.1, 958.4, 958.5	(See orthopedic conditions below)	
Low	Ophthalmologic disease	360-379	Ophthalmologic disease	360-379
	Gynecologic disease	617-629		
	Low-risk heart disease	393-429, except 415.1 and 416.0 and cases in heart disease categories above	Low-risk heart disease	393-429, except 415.1 and 416.0 and cases in heart disease categories above
	Gastrointestinal disease	530-579, except 577.0, 573.1 and 573.2 and cases in gastrointestinal catastrophes above	Gastrointestinal disease	530-579
	Urologic disease	593-609	Renal and urologic disease	580-609

(continued)

	Health Care Financing Administration		Veterans Administration	
Risk group	Diagnostic category	ICD-9-CM codes	Diagnostic category	ICD-9-CM codes
Low	Orthopedic conditions	712-739, 810-838, 840-848, excluding cases in severe trauma above	Orthopedic conditions	712-739, 810-838, 840-848
			Infectious and parasitic disease	001-136, 460-466, 472, 473, 474.0, 475, 476, 478.1, 478.2, 478.5, 680-686, 790.7
			Symptoms and ill-defined conditions	780-799
			Aftercare, rehabilitation, follow-up examinations	V40-V71
	All other conditions		All other conditions	

Appendix III

Comparison of HCFA and VA Chronic Conditions

Health Care Financing Administration		Veterans Administration	
Condition	**ICD-9-CM codes**	**Condition**	**ICD-9-CM codes**
Cancer	141-160.9, 162-172.9, 174-208.9	Malignant neoplasms	140.0-172.99, 174.0-208.9
Chronic liver disease	571-572.8	Chronic liver disease	571-572
Chronic renal disease	582-583.9, 585-587	Chronic renal disease	581-583, 585-586
Chronic cardiovascular disease	412-414.9, 426-429.1	Arteriosclerosis Atherosclerosis	414.0, 429.2, 437.0, 440
Chronic pulmonary disease	491-493.9, 496	Chronic obstructive pulmonary disease	491-496, 500-505, 506.4
Cerebrovascular degeneration, chronic psychosis	290-290.9, 294-299.9	Cerebral degeneration	290
Hypertensive disease	402-405.99, 412-414.9		
Diebetes	250.01, 250.1-250.9	Diabetes mellitus	250.01, 250.10-250.91
		Nutritional deficiencies	260-269, 425.7
		Metabolic and immune disorders	270-279
		Alcoholism	291, 303, 425.5
		Hemotologic disorders	282, 284
		Neurological disease	330-337, 340, 341, 343, 345

A CRITIQUE OF THE 1987 HCFA MORTALITY STUDY

BASED ON NEW YORK STATE DATA

STATE OF NEW YORK

DEPARTMENT OF HEALTH

OFFICE OF HEALTH SYSTEMS MANAGEMENT

Abstract

Recently, the Health Care Financing Administration (HCFA) published its 1987 mortality study, which identified hospitals nationwide that have significantly higher and lower mortality rates (referred to as high outliers and low outliers, respectively) than predicted by the HCFA statistical model. Neither this study nor its 1986 predecessor validated its findings by conducting quality of care record reviews.

The primary purpose of this study is to use record reviews conducted in New York State to draw inferences about the relative quality of care in HCFA outlier and non-outlier hospitals. Another purpose is to use New York data to explore two major criticisms of the HCFA study: (1) the paucity of severity of illness surrogates and (2) the aggregation of diagnoses with markedly different mortality rates into a common category.

The results indicate that, contrary to HCFA's prediction, the high outliers had significantly lower percentages of quality of care problems than the non-outliers. Low outliers had lower, but not significantly lower, percentages than non-outliers. Furthermore, there is potential for bias because of the aggregation of diagnoses. Also, it appears that the inclusion of additional severity measures, particularly whether or not the admission was scheduled, could alter the group of outliers substantially.

EXECUTIVE SUMMARY

In November 1987, the Health Care Financing Administration (HCFA) published a study based on 1986 national data that contrasts actual and predicted mortality rates (within 30 days of hospital admissions) nationwide. The predicted mortality rate was obtained by employing a statistical technique, logistic regression analysis, to predict the probability a patient will die within 30 days of admission to a hospital. The variables used to predict this probability include age, gender, principal diagnosis, additional diagnoses (up to four), number of prior hospitalizations, and status as a transfer patient from another hospital.

Patients are grouped into 17 distinct diagnostic categories by means of the principal diagnosis. The first 16 categories follow medical disciplinary lines and distinguish among high and low risk conditions. The categories are subdivided into high risk and low risk groups as follows:

High Risk Categories

Cancer
Cerebrovascular Accident
Severe Acute Heart Disease
Severe Chronic Heart Disease
Gastrointestinal Catastrophes
Metabolic/Electrolyte Disturbances
Pulmonary Disease
Renal Disease
Sepsis
Severe Trauma

Low Risk Categories

Opthalmologic Disease
Gynecologic Disease
Low Risk Heart Disease
Gastrointestinal Disease
Urologic Disease
Orthopedic Disease

In order to calculate the predicted mortality rate for a hospital, the predicted probabilities are summed for each patient in a specific diagnostic category, and then summed across the diagnostic categories. A confidence interval is calculated for each predicted rate, and the actual rate is compared with the range defined by the confidence interval. If the actual rate exceeds the upper (lower) bound of the confidence interval, the hospital is identified as a "high outlier" ("low outlier"). The presumption is that high outliers are more likely to provide substandard care and low outliers are more likely to provide better than average care.

The data are then aggregated across all diagnostic categories. Confidence intervals are again calculated and high and low outlier hospitals can be identified for the aggregate of all categories.

HCFA includes in its presentation the caveat that severity of illness has not been accounted for adequately. Nevertheless, the implication of the study is that high outlier hospitals are more likely to be providing substandard care and that low outlier hospitals are more likely to be providing higher quality of care. The information provided by HCFA is to be used by peer review organizations in choosing hospitals for review, and for consumers to use in selecting hospitals.

Of the approximately 6,000 hospitals reviewed by HCFA, 146 (2.4 percent) were high outliers for aggregate mortality and 180 (3 percent) were low outliers. New York's percentages were somewhat higher, with 10 high outliers and 10 low outliers. The outliers are as follows:

High Outliers

City Hospital Center at Elmhurst
Coney Island Hospital
Harlem Hospital Center
Kings County Hospital Center
Metropolitan Hospital Center
Nassau County Medical Center, East Meadow
North Central Bronx Hospital
Parsons Hospital
Queens Hospital Center
Woodhull Medical and Mental Health Center

Low Outliers

Adirondack Regional Hospital
Bellevue Maternity Hospital, Schenectady
Lenox Hill Hospital
Lewis County General Hospital
Loeb Center, Montefiore Medical Center
Mary McClellan Hospital
Medical Arts Center Hospital
New York University Medical Center
St. Francis Hospital, Olean
University Hospital of Brooklyn

It is notable that whereas all of the ten high outlier hospitals have 100 or more beds, only four of the ten low outlier hospitals have 100 or more beds.

The primary purpose of this critque is to use record reviews conducted in the New York State Department of Health (NYSDOH) study "Investigation of

Quality of Care Problems Associated with In-Hospital Mortality in New York State: An Identification of Critical Case Characteristics for Targeting Purposes" to test the validity of the HCFA study. Another purpose is to use New York State data to explore two major criticisms of the HCFA study: (1) the paucity of severity of illness proxies and (2) the aggregation of diagnoses with markedly different mortality rates into a common diagnostic category.

Before discussing the results, a short description of the NYSDOH study mentioned above will be provided. The study was conducted for the purpose of testing the ability of various hospital case characteristics to target cases for quality of care problems in hospitals. The characteristics were all resident on the Statewide Planning and Research Cooperative System (SPARCS) data base. In order to test the relative effectiveness of the case characteristics, random cases were also selected. Determinations of quality of care problems in the downstate region were made by State utilization review (UR) agents after reviewing medical records for evidence of either (1) care that caused or contributed to patient deaths or (2) care that departed from professionally recognized standards. Cases judged to evidence quality of care problems were reviewed by two or more board certified specialists.

Because of the stratified sampling plan that was used, the proportion of quality of care problems in targeted and non-targeted cases were reweighted in order to simulate a random sampling of cases. The results for HCFA outlier and non-outlier hospitals were then compared using appropriate statistical tests.

The results indicate that, as a group, HCFA's high outliers had significantly lower percentages of quality of care problems than non-outliers (hospitals that were neither high nor low outliers). Furthermore, although results for individual hospitals must be treated with caution because the sample sizes are much smaller than for the aggregate data, only one of the high outliers had a higher percentage of quality of care problems than the non-outliers. All others had lower percentages, and two were significantly lower.

Also, as a group, HCFA's four low outliers in the downstate region (the only low outliers reviewed in the study) did not have a significantly different percentage of quality of care problems than non-outlier hospitals.

With regard to the second investigation conducted in this critique (HCFA's method for aggregating diagnoses), there appears to be substantial potential for bias as a result of aggregating diagnoses with markedly different mortality rates. New York State data show that some hospitals may be unfairly disadvantaged because they have higher than average percentages of cases with high mortality rate diagnoses in certain diagnostic categories, and other hospitals may be receiving preferential treatment because they have lower than average percentages of cases in high mortality rate diagnoses.

The third focus of this critique was to compare, for outlier and non-outlier hospitals, the presence of severity of illness proxies not used by HCFA. The analysis indicates that a few severity proxies resident in SPARCS could have altered HCFA's results substantially if they had been used. For example, HCFA's outlier hospitals transferred only 1.1% of their patients to other acute care hospitals, compared with a 2.6% transfer rate for non-outliers. This variable has been used as a proxy because frequently transfer patients are severely ill.

The variable that appeared to be particularly discriminating among outlier and non-outlier hospitals was the percentage of unscheduled admissions. This variable has potential as a severity proxy because unscheduled admissions tend to be more severely ill than scheduled admissions. Whereas 38.3% of patients in low outlier hospitals were unscheduled, the percentages for non-outlier hospitals and high outlier hospitals were 52.5% and 60.9%, respectively. It would appear that if this variable had been used in the HCFA model, many of the differences between predicted and actual mortality rates in both high and low outliers could have been explained.

In conclusion, New York State data do not confirm the HCFA outlier designations. Nevertheless, HCFA is to be commended for attuning consumers, researchers, accrediting agencies and hospital administrators to the need to review outcomes of care. This study and the work of Dubois et al indicates that if the HCFA methodology were enhanced by clinical severity of illness measures or perhaps even a few more proxy measures, the results could be substantially improved. This study also demonstrates that further improvement could probably be realized if there was less aggregation (or perhaps more homogeneous aggregation) of diagnoses.

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Because it was one of the first states to mandate collection of total hospital discharge data, Maine became an ideal site for the application of the Small Area Analysis technique first proposed by Wennberg & Gittlesohn in 1973. In the early 1980's Wennberg was joined by Dr. Daniel Hanley of Maine in an effort to to convince Maine doctors of the importance and value of studying variations in medical practice. Their successful effort resulted in the founding of the Maine Medical Assessment Foundation [MMAF]. As everywhere, analysis of Maine data revealed marked variation in hospitalization for many procedures and conditions while for others little or no variation existed. For non-variable conditions such as treatment of hernia and hip fracture, it was clear that physicians were in agreement regarding the appropriate treatment. However, when rates of hospitalization for a given diagnosis were shown to vary from 5 to 10 times among different areas, it became clear that the most significant cause was uncertainty among doctors as to the "best method" of treatment.

After initial funding by The Commonwealth Fund and the Robert Wood Johnson Foundation, the program has been generously funded by Maine Blue Cross/Blue Shield. While this major health insurer has great concerns regarding the cost of medical care, its interest in quality of care and willingness to consider this project as a research effort has allowed the assessment project to proceed in an independent, scientific manner. Seven specialty study groups [internal medicine, pediatrics, obstetrics & gynecology, urology, orthopaedics, opthamology and family practice] were established, each under the direction of a study group leader. Each of the study groups has effectively evaluated variations in its field. When significant variations have been identified, the data is carefully refined to insure accuracy of diagnoses and procedures. Meetings of involved specialists from high, median and low rate areas are held in a non-threatening, confidential, educational setting. Discussion of the medical problem provides a format for clinical discussion, feedback of information and peer pressure.

In briefly summarizing six years of work, two conclusions can be drawn. First, the process of specialty study group evaluation with its educational feedback process has been remarkably successful in producing reduction in variable rates of hospital admissions and doing so in a manner that is completely controlled by the treating physician and which has no adverse effect on the quality of care. Second, and equally importantly, we have learned that even when consensus regarding the best method of treatment is lacking, variations in practice patterns will quickly diminish secondary to peer pressure and physician discomfort with being an "outlier" [even in a confidential setting]. However, without underlying consensus variations will recur in the same area or develop in new ones. This fact is not surprising since there is no reason to expect physicians to admit and treat patients in similar patterns if they are not in agreement about the most appropriate method of treatment in the first place. In almost every medical specialty there are diagnoses and procedures for which variations in practice patterns occur.

An example of this phenomenon is illustrated in exhibit 1. Admissions for pediatric medical conditions occured at two and one-half times the expected rate in an urban area. Feedback was provided to local pediatricians by the hospital service chief in 1982 [F1] and the rates dropped. However, when that physician retired [E], monitoring of admission rates ceased and the rates began to rise. The Pediatric Study Group again provided information and feedback to the area physicians [F2], and a prompt response occured. A different problem is illustrated by the Orthopaedic Study Group. Exhibit 2 demonstrates a marked increase in surgery for herniated lumbar disc in a Maine city. The sharp increase in these rates occured after three new surgeons began to practice in this community. That the feedback process was successful can be seen as rates dropped to the expected rate soon after feedback. While rates have remained at the expected number in this area, analysis of statewide data has demonstrated rising rates of surgery in three different areas. The surgical treatment of disc injury has long been controversial and consensus among physicians is clearly lacking.

While the focus of the Maine Medical Assessment Foundation remains in the area of appropriateness and quality of care, there are significant cost implications. It is estimated that the activities of the Foundation's seven study groups encompass 90% of medical hospital admissions and 50% of surgical cases, or 75% of all hospitalizations. Hospital and physician costs [related to hospital care only] in Maine- approximate $867 million annually. Seventy-seven percent or $667 million of these costs are impacted currently by the work of the study groups. The cost savings to Maine citizens, insurors, and state and federal government which have been realized as a direct result of the MMAP's activities is $1.5 million dollars annually. With an budget of approximately $250,000 the cost benefit ratio of this project is six to one. While cost containment has never been the direct goal of the assessment program, we are pleased to note the savings which have resulted, and even more pleased that they have come about in a voluntary, non-coercive manner which has enhanced quality of care and gained the acceptance and appproval of the large majority of Maine's doctors.

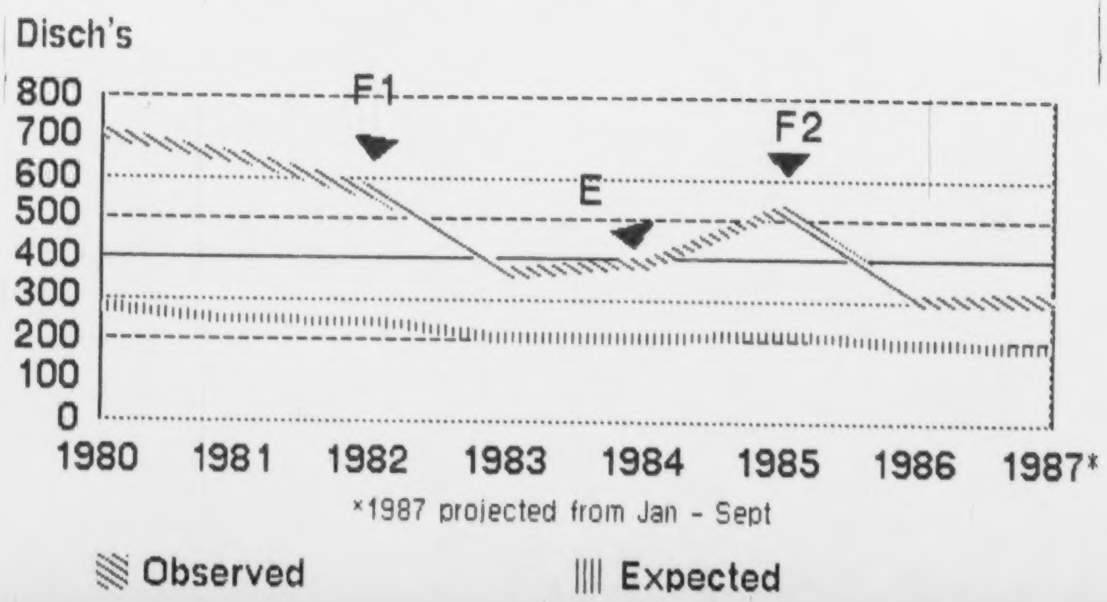
The record of the Maine Medical Assessment Foundation demonstrates clearly that physicians will voluntarily participate in and respond to programs which analyze practice pattern variation, but we have also learned that where consensus regarding treatment does not exist, variations will recur. We also recognize that our work [and that of others] fails to answer a major question. That is - "What is the right rate?". We have used the average statewide rate for a given diagnosis or procedure as a basis for comparing areas within the state, but we realize that these rates simply represent a average of physician treatment decisions within the state. Indeed, there are significant variations between states, regions and nations. The conclusion is that for highly variable medical conditions the appropriate rate of treatment is unknown. Selecting the lowest rate as the correct one is as inappropriate as selecting the highest. The problem posed by lack of physician consensus and resultant uncertainty about the "right rate" has major cost and quality implications. Its solution will come only through outcome studies.

Current medical literature and education fail to adequately educate and inform doctors about the long term, patient-oriented results of many treatments, hence the variations. Outcome studies, such as the recently completed Maine prostatectomy study indicate that patients' perceptions of their treatment and their willingness to accept various degrees of risk to achieve benefits will vary markedly among different individuals. Intuitively, physicians have always known that two different patients with the same medical problem may have radically different perceptions of the degree of their disability and pain and of their willingness to accept the risks, benefits, and expense of treatment. What we lack is a better way to measure those factors and a method to engage the patient centrally in the decision-making process while simultaneously eliminating physician bias. The concept of "Standard Setting" based on current knowledge does not solve this problem. The listing of criteria for treatment, expected outcomes and potential risks may not provide the individual patient and his/her physician with adequate information regarding the ultimate utility of treatment to that individual. Outcome studies which focus not only on the medical aspects of care, but also carefully assess patients' perceptions of the benefits and changes in quality of life [both positive and negative] as a result of that care, provide an important step in dealing with this problem. When we are able to accurately measure patient-oriented outcomes of medical treatments, it will then be possible to develop interactive information systems with which both doctors and patients can more accurately determine the best method of treatment for each individual.

The result will be a more focused approach on individual clinical problems and decision making, a likely decrease in frequency of many expensive medical procedures, and improved quality of care. Since it is the goal of all participants in the health care arena to provide the highest quality of care at the lowest cost, the funding of outcome studies seems a logical and essential step in this process.

Exhibit 1

CENTRAL MAINE AREA CHILDREN
4 PEDIATRIC MEDICAL DRG'S

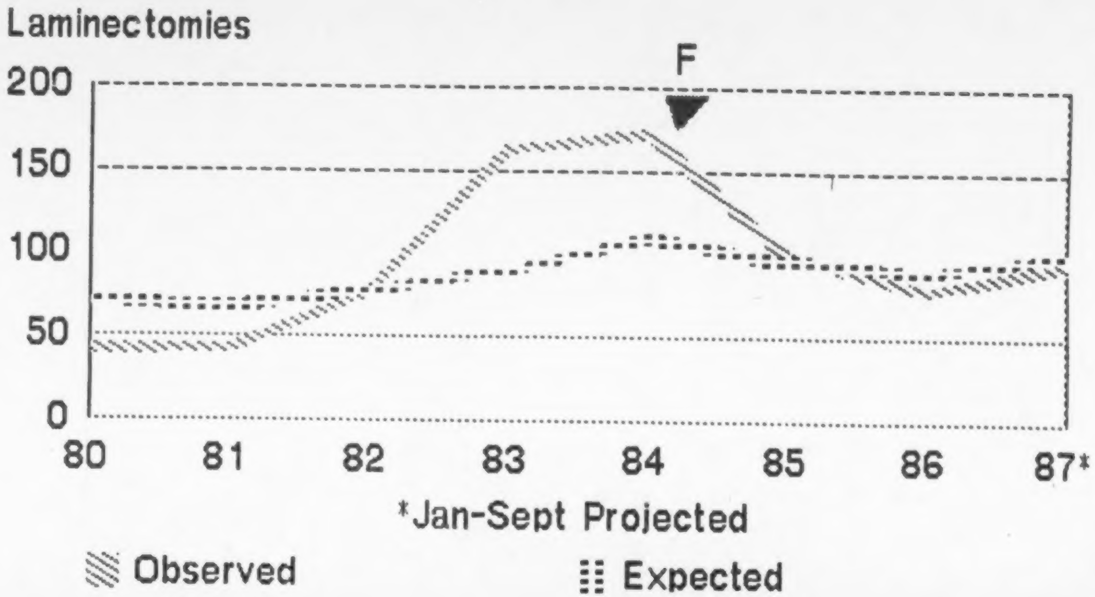


*1987 projected from Jan - Sept

Exhibit 2

1980 - 1987 LAMINECTOMIES, ALL PAYERS

URBAN AREA A



STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee On Health
Committee On Finance
United States Senate

Presented by

Robert E. McAfee, M.D.
John T. Kelly, M.D.

RE: Quality Assessment and Quality Assurance Activities

July 11, 1988

Mr. Chairman and Members of the Committee:

My name is Robert E. McAfee, M.D. I am a physician in the practice of surgery in Portland, Maine and I am also a member of the Board of Trustees of the American Medical Association. With me today is John T. Kelly, M.D., Director of the AMA's Office of Quality Assurance. Accompanying us is Ross Rubin, Director of the AMA's Division of Legislative Activities. The AMA is pleased to testify concerning the important issues of quality assessment and quality assurance.

Quality assessment and quality assurance are all part of the broad range of activities designed to assist the physician and the patient in selecting the most appropriate course of treatment for the individual patient. The AMA strongly supports these efforts. Every day we acquire new knowledge about the human body and the most effective ways to treat disease and disability. As we expand our knowledge base, we can identify treatments that better serve our patients. However, we must never lose sight of the primary focus of treatment -- individual patients with individual needs and expectations.

Providing proper medical care is an enormously complex process in which many issues, subjective as well as objective, must be considered. For example: What treatment options are available? Is there medical certainty in the area or is there reasonable scientific debate? How does the patient perceive his current condition? What are the patient's expectations and are those expectations reasonable? What individual values does the patient bring to determining the desired outcome? What quality of life issues should be considered? How should societal factors be integrated in the individual treatment decision? Although some aspects of these issues can be quantified for research purposes, many can not.

AMA QUALITY ACTIVITIES

Maintaining and improving the quality of medical care has been the central purpose of the AMA since it was established in 1847. Last year, the AMA House of Delegates adopted the following statement on the quality of medical care:

> The American Medical Association is unequivocally committed to ensuring the provision of high quality medical care to all individuals. "High quality" medical care consistently contributes to the improvement or maintenance of the quality and/or duration of life. As the unique representative of physicians, who are their patients' advocates, the American Medical Association will continue to actively foster, pursue and evaluate definitions and measurement techniques for the quality of medical care in all practice settings. As a part of this effort, the American Medical Association will aggressively promote organized and systematic quality assessment and quality assurance activities as an integral aspect of the day-to-day practice of every physician, regardless of the treatment setting.

This statement reflects the continued and increased commitment of the AMA to quality of care issues.

Essential Elements for Quality

The AMA has identified eight essential elements that characterize care of high quality. The care should:

(1) Produce the optimal possible improvement in the patient's physiologic status, physical function, emotional and intellectual performance and comfort at the earliest time possible consistent with the best interests of the patient;

(2) Emphasize the promotion of health, the prevention of disease or disability, and the early detection and treatment of such conditions;

(3) Be provided in a timely manner, without either undue delay in initiation of care, inappropriate curtailment or discontinuity, or unnecessary prolongation of such care;

(4) Seek to achieve the informed cooperation and participation of the patient in the care process and in decisions concerning that process;

(5) Be based on accepted principles of medical science and the proficient use of appropriate technological and professional resources;

(6) Be provided with sensitivity to the stress and anxiety that illness can generate, and with concern for the patient's overall welfare;

(7) Make efficient use of the technology and other health system resources needed to achieve the desired treatment goal; and

(8) Be sufficiently documented in the patient's medical record to enable continuity of care and peer evaluation.

We believe that these essential elements of quality care provide a logical framework around which to organize professionally conducted quality assessment programs and on which to construct specific criteria for such assessments. In addition, when these elements are followed patients have a better frame of reference to make judgments about the quality of care they receive.

Guidelines for Quality Assessment

The AMA has developed guidelines for the establishment of quality assessment systems. These guidelines are intended to apply to any system aimed at measuring quality of care, whether voluntary or mandated, and whether sponsored or conducted by a medical society, hospital staff, third-party payor, foundation, corporate reviewer or federal agency. The key guidelines are as follows:

- The criteria used to measure quality of care should be developed and agreed upon by the physicians whose performance will be measured in the study. Physician participation is imperative not only to the acceptability of the assessment process, but to assure that the criteria used are medically appropriate.

- The purpose of a quality assessment program should be to improve medical practice by providing physicians with information that will enhance patient care. The information gleaned from the research should be used to educate physicians to modify their practice patterns where indicated rather than to punish them. Quality assessments should not have as their goal the reduction of health care costs. In fact, the knowledge acquired from quality assessment research could lead to increased levels of care being provided by physicians.

- Quality assessment studies should be conducted on a prospective as well as a retrospective basis. In a retrospective study, it may be difficult to distinguish between the effects of care provided and other factors which can also influence outcome, such as patient age, past history and lifestyle, stage of disease, and attitude toward illness. The identification of "expected" outcomes on a prospective basis, and subsequent comparison with actual results, may allow better identification of individual risk factors and the allocation of patients to similar risk categories better suited to analysis.

- The evaluation of "intermediate" rather than "final" outcomes is an acceptable technique in quality assessment. It is often more feasible to use intermediate outcomes or immediate treatment results as indicators of quality rather than long-term morbidity and mortality data. In addition, the direct effects of care received are progressively obscured over time.

- The quality assessment process itself should be subject to continued evaluation and modification as needed. The criteria upon which quality of care is assessed, and the quality assessment methodology itself, must be continuously reviewed and revised by the physicians using them to reflect increased scientific knowledge, improved technologies, availability of resources, and other developments relating to the demand for and provision of medical care.

Quality Assessment Research

AMA quality efforts since its founding have been based on the use of the scientific method to improve medical care. The AMA strongly supports quality assessment and outcome research that will provide a better scientific basis for clinical management decisions. Well-conducted quality assessment research could likewise improve both treatment decisions and quality assurance programs. When presented with well-documented data, physicians respond by adjusting their patient management practices to optimize care. Development of such data is welcome.

We are, however, concerned that inappropriate conclusions may be drawn and ill-advised policy decisions may be made based on the results of such research. The complex issues involved in providing medical care to individual patients often cannot be reduced to algorithms and mathematical formulas. For example, based on the results of a quality assessment study, a third-party payor could decide to eliminate reimbursement for a particular procedure because the procedure appears to be associated with a greater risk of morbidity and mortality than other treatment modalities. However, the study may be flawed because it failed to adjust properly for patient characteristics or other important variables. In addition, the procedure with the higher morbidity and mortality risk may be the most appropriate treatment for certain patients if, along with the greater risks, there are greater potential health benefits or if other procedures prove to be ineffective for the particular patient. In order to help ensure that the results of a quality assessment study are interpreted and used properly, the results, in all cases, should be subject to review and evaluation by practicing physicians through the peer review process before policy decisions are made based on the studies. The results should be used as guides for physicians, not as absolute rules, so that physicians can tailor medical care to meet the unique medical needs of each individual patient.

AMA Activities Concerning Geographic Variations

A substantial and growing body of research on geographic variations in the utilization of health care services has identified significant area-to-area differences that cannot be explained by demographic or epidemiological factors. Variations in the utilization rates for specific medical and surgical procedures can be caused by many interrelated factors. Explanations for variations range from variations in patient needs to inappropriate utilization. However, recent research indicates that a key reason for variations is differing professional opinions concerning the appropriate course of treatment for certain conditions. Research indicates that variations may be due to differences in patients' expectations and demands. Research also suggests that variations may be indicators of underservice in low-rate areas rather than overutilization in high-rate areas.

The AMA has been strongly supportive of research concerning variations in utilization. We have endorsed the feedback of such data to physicians through the specialty panel approach. Such medical assessment programs have been conducted by many state medical associations including, for the past seven years, the Maine Medical Association. Under this program, an advisory committee that includes individual physicians and representatives of the insurance industry, hospitals, and state agencies was established. The advisory committee reviews hospital discharge data and identifies variations in specific medical and surgical procedures among areas of the state. Specialty-specific study groups of physicians then review inpatient utilization rates for their own specialty. Physicians with practice patterns inconsistent with the norm are identified and provided an opportunity to review data on their own practice patterns within an educational framework and, if warranted, to adjust their practice patterns. This program, which can serve as a model for other quality assessment efforts, has resulted in cost savings without compromising the quality of patient care.

In 1986, the AMA published a booklet entitled Confronting Regional Variations: The Maine Approach, which summarizes the Maine Medical Association's ongoing medical assessment program. The publication has been distributed to other medical societies interested in implementing regional variations studies. Also in 1986, the AMA sponsored a two-day seminar on "Regional Variations in the Utilization of Health Care Services." Dartmouth Medical School and the National Center for Health Services Research cosponsored the seminars.

The AMA supports the Health Care Financing Administration/American Medical Review Research Center's (AMRRC) PRO-based demonstration study of small area variations in hospital care among Medicare beneficiaries. We have urged that in selecting the twelve PROs for the study AMRRC should give due consideration to PROs in states in which the medical society has begun regional variations studies or has demonstrated interest in becoming involved in variations research and physician feedback systems.

AMA Technology Assessment Activities

The appropriate utilization of any medical technology must proceed from a thorough understanding of the safety and effectiveness of that technology. The American Medical Association has developed and disseminated accurate and balanced evaluative information on the appropriate utilization of many medical technologies. At present, the AMA has three major technology assessment activities:

The Diagnostic and Therapeutic Technology Assessment (DATTA) program
AMA Drug Evaluations
The Council on Scientific Affairs.

These programs evaluate drugs, devices, procedures and techniques utilized in the practice of medicine. The programs evaluate emerging and new technologies, those that are in widespread use and those that are possibly obsolete. Examples of recent evaluations include radial keratotomy and the Garren gastric bubble. These programs rely on a qualitative analytical approach and utilize approximately 2,500 expert physician consultants across the broad range of medical specialties. The evaluations of the DATTA project and the reports of the Council on Scientific Affairs are communicated to physicians primarily through publication in JAMA.

The AMA's Department of Technology Assessment also is deeply involved in research on new ways to assess technologies. For the past two years, the DATTA project has worked with Dr. David Eddy of Duke University to integrate DATTA's qualitative approach with his quantitative methodology for the estimation of the magnitude of outcomes due to the application of a specific technology. This collaboration already has resulted in the publication in JAMA of a major study.

Technology assessment provides information essential to identify the appropriate uses of medical technology. Technology assessment also provides the knowledge base from which quality assessment proceeds. A more comprehensive description of AMA-Drug Evaluations, a comprehensive volume published every 3 years, and the Council on Scientific Affairs are contained in the appendix.

AMA Office Of Quality Assurance

In furtherance of our commitment to quality care, the AMA has established an Office of Quality Assurance that will enable the Association to be a major force in the fields of quality assessment and quality assurance. The Office will develop a long-range plan for quality assurance in medical care, coordinate existing quality activities within the AMA, act as liaison with organizations with major quality assurance activities, and monitor and evaluate quality assurance initiatives undertaken by the AMA and other organizations. In addition, the Office of Quality Assurance will provide information to physicians and the public to improve the quality of medical care.

CONCLUSION

The AMA has a long history of involvement in a wide range of quality assessment and quality assurance activities. In recent years, the AMA has developed a number of new quality assessment and quality assurance initiatives. These initiatives include the identification of essential elements that characterize high quality care and the establishment of an Office of Quality Assurance.

The AMA strongly supports quality assessment research and has developed guidelines for quality assessment systems. These guidelines emphasize that the goal of a quality assessment program should be to educate physicians so that they can provide better patient care. In addition, physicians should be involved in the evaluation and interpretation of the results of these studies.

It is also important to recognize that efforts in the area of outcome assessment and effectiveness research may serve to decrease costs or increase costs. They may encourage certain treatments and discourage others. What must be available, however, is flexibility for physicians to tailor medical care to meet the individual needs of their patients.

We commend the early research that has contributed tremendously to our understanding of geographic variations. Such research has helped us to improve the quality of medical care and identify the range of questions that need further study and answers. We also believe strongly that outcomes research in many other areas is needed in order to assess the benefits of the treatment options available to physicians and patients. Such efforts will contribute to improving the quality of care provided to the public. We look forward to working with Congress and other interested parties on this important health issue.

I will be pleased to answer any questions members of the Committee may have.

APPENDIX

AMA'S ACTIVITIES IN IMPROVING QUALITY OF CARE

AMA Drug Evaluations (DE)

The publication *AMA DE* provides physicians and other health care professionals with up-to-date, comparative and unbiased information on the *clinical use* of more than 1,900 prescription and nonprescription drugs. *DE* includes information on the uses (including medically accepted unlabeled uses), adverse reactions, precautions, pharmacokinetics and dosages of drugs. Chapters are prepared initially by the professional staff of the AMA's Department of Drugs based on the current scientific literature. They are then reviewed by distinguished consultants, the medical staffs of drug manufacturers, and by members of the American Society for Clinical Pharmacology and Therapeutics. Thus, the information contained in *DE* represents a distillation of the current scientific literature plus the combined expertise of many experienced clinicians.

Diagnostic and Therapeutic Technology Assessment (DATTA)

The AMA evaluates new medical technologies through the DATTA program. Critical to the success of this program is a reference panel of more than 1,600 expert physician scientists. Panelists encompass all major medical specialties, practice in all types of settings and are distributed across all geographic regions of the country. Approximately 40 to 100 physicians participate in each DATTA evaluation.

DATTA panelists:

1) evaluate the safety and effectiveness of particular medical technologies (drugs, devices, and procedures) for specified indications,

2) provide comments reflecting their knowledge and professional experience on the risks and benefits associated with the technology and on the indications for use, and

3) rate the technologies as established, investigational, or unacceptable.

Completed evaluations of a technology reflect a consensus opinion of the expert consultants balanced with the peer-reviewed medical literature. The primary means of disseminating a DATTA evaluation to the practicing medical community is through publication in the *Journal of the American Medical Association*. Each year the DATTA program responds to over 1,000 requests for opinions and information from physicians, patients, hospitals, manufacturers, federal regulatory agencies, and public and private third party payors.

Council on Scientific Affairs (CSA) Reports

The AMA Council on Scientific Affairs prepares reports on scientific and medical issues concerning quality of care. Reports on magnetic resonance imaging and intrauterine fetal surgery are examples of recent CSA reports that provide valuable medical insights. These reports are published regularly in the Journal of the American Medical Association, thereby enhancing their impact on medical practice.

Joint Commission On Accreditation Of Health Care Organizations (JCAHO)

The AMA has been a corporate member of JCAHO since its formation in 1951. All JCAHO-accredited hospitals must have a written quality assurance program. In addition to hospitals, the JCAHO currently has accreditation programs for ambulatory care facilities, psychiatric programs (including substance abuse), long-term care facilities and hospices.

Medical Education

- Liaison Committee on Medical Education (LCME)
  The AMA and the Association of American Medical Colleges formed the LCME in 1942. The LCME is the accrediting body for medical education programs in the United States and Canada that lead to the M.D. degree.

- Accreditation Council for Graduate Medical Education (ACGME)
  The AMA is one of five member organizations of the ACGME, the national standard-setting and accrediting body for graduate medical education. The ACGME establishes training requirements and sets standards for over 6,000 residency programs throughout the country.

- Accreditation Council for Continuing Medical Education (ACCME)
  The AMA is one of seven national organizations that comprise the ACCME. The ACCME participates in the direct survey and accreditation of approximately 475 sponsors of national programs of continuing medical education and recognizes the accreditation of almost 2,000 sponsors of continuing medical education, surveyed and accredited by state medical societies.

- Committee on Allied Health Education and Accreditation (CAHEA)
  In collaboration with forty-nine medical specialty and allied health professional organizations, the AMA established this accrediting agency to ensure the establishment of high standards of quality for educational programs in twenty-five allied health professions.

Medical and Scientific Publications

The Journal of the American Medical Association (JAMA), with a circulation of over 600,000 in almost 150 countries, is widely recognized as one of the preeminent medical publications in the world. JAMA gives physicians the state-of-the-art medical information they need to provide quality patient care. The AMA publishes nine medical specialty journals. In addition, the AMA recently published a booklet for patients concerning quality entitled "Seeking Quality Medical Care: What You Should Know."

Medical Licensure And Credentialing Physician Masterfile

o Physician Masterfile

The AMA maintains a Physician Masterfile which contains current and historical information on all Doctors of Medicine and Osteopathy in the United States — both members and non-members of the AMA. Data are kept current through intensive data collection and monitoring techniques. Through the Physician Masterfile, the AMA provides a physician profile service that is widely used throughout the medical community as a primary source to verify credentials whenever a physician applies to a: 1) hospital for staff privileges; 2) state licensing board for medical licensure; 3) medical school for faculty appointment; or 4) county, state or specialty society for membership. Each year, the AMA supplies over 200,000 physician profiles for use in the credentials screening process.

o Licensure Action Alert Letters

Final disciplinary actions taken by state boards of medical examiners are reported monthly to the AMA by the Federation of State Medical Boards. The AMA automatically alerts state licensing boards of actions taken by other boards when Physician Masterfile records indicate that a physician has held or currently holds multiple state licenses. The purpose of this alert is to prevent a sanctioned physician from crossing state lines to practice medicine.

OPENING STATEMENT FOR FINANCE SUBCOMMITTEE ON HEALTH HEARING ON PATIENT OUTCOME ASSESSMENT RESEARCH

JOHN D. ROCKEFELLER IV

July 11, 1988

Mr. Chairman, I want to commend you for holding this hearing on patient outcome assessment research. In March, when I signed on as an original cosponsor of your bill, I was honored to join you in this effort to increase our understanding of the effectiveness, appropriateness, and quality of medical care.

Last year, as a result of the budget summit agreement, this Committee was forced to cut the Medicare budget by $5.5 billion dollars for fiscal years 1988 and 1989. None of us take cutting the Medicare budget lightly. When forced to do so, the effect of these cuts on Medicare beneficiaries and the medical care they receive is uppermost in all our minds.

I welcome patient outcome research as a way to make sure that Medicare and Medicaid beneficiaries continue to receive high quality medical care. Health care spending has grown at a tremendous rate since Medicare and Medicaid were first enacted in 1965. The change to a prospective payment reimbursement system from a cost-based reimbursement system was an attempt to get a handle on federal expenditures for hospital care. The Congressional advisory commission on physician payment is likely to recommend specific changes in physician reimbursement in the very near future.

Mr. Chairman, we can not continue making changes in the way we pay for medical care without carefully monitoring possible side effects on the quality of health care. We must make a committment to pursue an agenda of measuring quality. We need good information on quality so we can make the right decisions in the future.

I look forward to hearing and learning from the witnesses today. It is vital that we aggressively pursue and adequately fund research on the quality of medical care and I am pleased to be part of this effort. Our future decision-making on health care spending must be linked with information on quality. S. 2182 will help us achieve this goal.

Statement of William L. Roper, M.D.
July 11, 1988

Mr. Chairman, I am pleased to discuss with you an important new initiative of the Department of Health and Human Services -- one which we believe will promote the quality of health care for Medicare beneficiaries. Our Effectiveness Initiative is intended to foster "what works" in the practice of medicine. The initiative has three parts which include:

- Conducting Patient Outcome Assessment Research;
- Enriching and sharing HCFA's clinical and claims data to encourage effectiveness research; and,
- Disseminating the results of this research to the medical community and to the public.

The essential challenge facing HCFA is to find a way to shape the large data bases we have amassed into information which will be useful in the everyday practice of medicine. To accomplish this goal, our present activities include: monitoring health trends in the Medicare population, analyzing variations found through these monitoring techniques, assessing the different interventions used to treat patients, and providing feedback to physicians about our results.

I have no doubt that our efforts and those of others can transform the practice of medicine. What is exciting for us, and I believe for the medical community as well, is that this change will be realized not through greater government regulation of the medical profession, but by putting good information into the hands of the people who want it most -- physicians and patients.

Sharing information with the public is a goal that we strongly advocate. For example, once again HCFA plans to release hospital mortality information in December. We will also begin targeting information to consumers later this year when we release information on the quality of nursing home care. Our goal is to make necessary information available to consumers and the health care community on the quality of care provided in institutions and on what types of medical treatments are clinically effective.

Let me be clear that HCFA does not lay exclusive claim to this area, nor is its agenda immutable: we depend on input from all those concerned with providing high quality care, and especially seek advice from practicing physicians. We have worked with representatives of many groups throughout the evolution of this initiative, and look forward to their continued support. We will also need the support of Congress, and look forward to keeping you informed of our results.

Mr. Chairman, I am pleased to be here today to discuss with you an important new initiative of the Department of Health and Human Services. Secretary Bowen has already testified before you on March 3, 1988 on the importance of his initiative. It is one which we believe will promote quality of health care for Medicare beneficiaries and for all Americans. Quite simply, our Effectiveness Initiative is intended to foster "what works" in the practice of medicine.

The Department's Initiative has three parts which include:

- Conducting Patient Outcome Assessment Research;
- Enriching and sharing HCFA's clinical and claims data to encourage effectiveness research; and,
- Disseminating the results of enhanced Departmental research to the medical community and to the public.

We recognize that this is a full and challenging agenda, and one which cuts across all health components of the Department. And, I want to state for the record that HCFA does not lay exclusive claim to this area, nor is its agenda immutable. We recognize that many researchers, some of whose work I will mention later, have grappled with the effectiveness question for several years. As relative new-comers we believe our unique role in the overall effort involves bringing HCFA's substantial data and other resources into the arena.

I have no doubt that our efforts and those of others in this area can transform the practice of medicine in this nation. What is exciting for us, and I believe for the medical community as well, is that this change will be realized not through greater government regulation of the medical profession, but by putting good information into the hands of the people who want it most -- physicians and patients.

Outcomes of Care

In order to explore effectiveness, we must be concerned with the outcomes of care. Examples of outcomes of care include rates of mortality and disease, levels of disability, and cost. When we have sound scientific evidence that the medical treatments we purchase yield favorable outcomes, and that those treatments are being appropriately performed on the individuals who could benefit from them, we will have constructed an effective health services delivery system. However, while such a system is our goal, the evidence collected to date leads us to believe that we have far to go in achieving it. Let me share some of this evidence with you.

The Evidence

Modern medicine is an extraordinary work of reason. It is an elaborate system of specialized knowledge and procedural rules. Indeed, the medical advances of the past 50 years have made our generation the fortunate recipient of the most sophisticated medical interventions to date. Modern medicine has changed the very fabric of civilization by alleviating disease and suffering, and by extending the length and quality of life for millions. Yet, the practice of medicine is an art as well as a science. As such, while much of medicine has underpinnings in biomedical research, it has also evolved through the subjective judgements of individual physicians, based on their experience and the experience of their colleagues.

The uncertain nature of medicine is evident in the clear differences in physician practice patterns observed by health services researchers. For example, there is great variability in the numbers and types of procedures performed by physicians, even within small, apparently similar, communities. Much of the ground-breaking work in this area was done by Dr. John Wennberg of Dartmouth Medical School. In the early 1970's, Dr. Wennberg revealed that some communities in New England had very high rates of tonsillectomy while other communities had very low rates. Children in the low use areas did not appear to experience adverse health outcomes as a result of foregoing the procedure. As a pediatrician, I know that practice patterns were scrutinized and subsequently changed because of his work and the work of others, not only in New England but nationally as well. Today, far fewer children are needlessly exposed to this surgery.

Dr. Wennberg's most recent work involved assessing alternative techniques for performing prostatectomy surgery. Medicare claims and other data were used to analyze the frequency of death and complications accompanying each alternative. Dr. Wennberg concluded that while controlled clinical trials are often necessary, alternative surgical interventions from actual medical practice can be evaluated to obtain important information on what works in the practice of medicine. His results underscore the potential value of effectiveness research.

Drs. Robert Brook and Mark Chassin and their colleagues at the RAND Corporation lend another intriguing dimension to the problem. Their HCFA-sponsored research has revealed that some procedures which are quite valuable in treating many patients are performed unnecessarily on others. They report that as many as 17 percent of coronary angiograms and upper gastrointestinal endoscopies and 32 percent of carotid endarterectomies are performed inappropriately. And, contrary to what you might naturally assume, the percentage of inappropriate procedures is similar in areas where the procedures are performed often and in areas where the procedures are performed infrequently. Clearly, the inappropriate use of at least some procedures is widespread. These findings are significant in terms of quality, cost containment, and medical ethics.

Last, allow me to mention the contributions of Dr. David Eddy of Duke University. Dr. Eddy has shown that the scientific evidence substantiating the effectiveness of many current medical practices is lacking. For example, he notes that a literature search of the merits of angioplasty versus bypass surgery for a particular type of vascular disease turns up little conclusive evidence on which alternative to choose for a given patient. According to Dr. Eddy, most of the "evidence" found on effectiveness in the literature is of questionable validity, and further, even when the evidence is good, it may be presented in a manner that practicing physicians are largely unable to interpret. Clearly, the quality of research must improve, and the findings must be presented in a way to make it understandable to physicians, or the link between effectiveness research and the actual practice of medicine will remain a weak one.

I point to these three research efforts because I believe they highlight some of the important questions being examined by effectiveness research. We are confronted with evidence of enormous variation, often without any apparent medical justification; a significant percentage of unnecessary procedures being performed, some of them very risky for the patient; and practicing physicians who often do not have access to the information they need to make good decisions, or who have information but find it difficult to interpret.

HCFA strongly believes it has a pivotal role to play in resolving this unacceptable state of affairs. We see our role as a facilitator in encouraging research by conducting our own research, sharing useful data, providing funds, helping to ask the right questions, and serving as a coordinating focal point for the efforts of the many parties involved. Let me mention several of our activities in this regard.

The HCFA Initiative

This year, the United States will spend $550 billion on health care, approximately 11.5 percent of the gross national product. The Medicare and Medicaid programs alone will spend about $120 billion. Given the magnitude of these expenditures and the importance our citizens place on quality health care, the lack of evidence about the effectiveness of medical treatments is an issue we cannot ignore. The HCFA effort on medical effectiveness can be grouped into three broad areas: enhanced data collection, coordination and sharing; increased emphasis on research by HCFA as well as other researchers; and increased levels of information dissemination to physicians and to the public.

Data

As the largest health insurer in the nation, HCFA has unique access to clinical and billing data, and we are eager to make it available for qualified effectiveness research. On May 3, 1988, HCFA published a notice in the Federal Register notifying the public that, this summer for the first time, a Medicare Part A information file would be available to researchers. The file will contain important health-related information, but patient names and other personal identifiers will be encrypted to protect beneficiary privacy. We are confident that offering comprehensive, national data will encourage research in this area.

We are also developing methods for using the data we currently collect in new ways. For example, we are finding ways to link inpatient and outpatient information, and to link our data with data from the National Cancer Institute cancer registries and the National Institute of Diabetes and Digestive and Kidney Diseases' Renal Disease System. Linking data this way provides us with a more complete profile of patients over time. In the future, we envision incorporating HCFA data files with those of private payers. This information could be used for effectiveness research provided strict safeguards are present to ensure confidentiality.

Further, HCFA developed and has begun testing a method for routinely collecting from Peer Review Organizations clinical data which can then be linked to claims data. This clinical information will lead us to the development of a Uniform Clinical Data Set which we believe holds great promise for collecting the key data elements necessary for effectiveness research.

Research

The challenge now facing HCFA is to find a way to shape the large data bases we have amassed into information which will be useful in the everyday practice of medicine. In addition to providing data to the research community, we are currently responsible for numerous research and demonstration projects on effectiveness. HCFA views its effectiveness research as a four-step process involving monitoring trends in health care, analyzing variations found through these monitoring techniques, assessing the different interventions used to treat patients, and providing feedback to physicians.

Monitoring Trends and Analysis of Variations: HCFA has in place a system to characterize the health of the Medicare population, monitor the outcomes of different interventions, and screen for emerging health care trends. For example, we collect annual statistics on mortality rates and hospital admissions. This type of monitoring often uncovers inconsistencies, or variations, in health care which we then analyze further. For example, we are currently using our data base to study variations in hospitalizations and re-hospitalizations across large and small areas. We also monitor the outcomes of specific interventions for the Medicare population, such as hospitalization for myocardial infarction.

Assessment of Interventions: Once trends or variations in medical care are identified, a more detailed investigation of the causes is needed. Often, such variations are the result of the effectiveness of interventions used to treat patients. For example, we are nearing completion on a project which links Medicare claims information with data abstracted from 29,000 medical records obtained from the PROs. We are using this vehicle to collect data for further studies on several procedures and conditions including cholecystectomy, prostatectomy, acute myocardial infarction, congestive heart failure, coronary revascularization, and pulmonary disease.

Feedback and Education: The information produced will have limited usefulness unless it finds its way into the hands of physicians. Several approaches could be used to accomplish this. The PRO system is one natural vehicle, but other entities should play key roles, including professional societies, medical schools, and the Public Health Service. I want to make very clear that the intent of this initiative is to provide information on the effectiveness of medical procedures: it is not our intent to rate the performance of individual physicians.

While still preliminary, I would like to share with you a few of our findings. This first graph (attachment 1) displays mortality rates following coronary revascularization. As you can see, our monitoring has revealed that, for the Medicare population, the death rate following bypass surgery is consistently higher than the death rate following angioplasty over a two-year period. After adjusting for many risk factors including age and other health conditions, however, the difference largely disappears. Knowing this, our next step will be to investigate which procedure works best on which patients.

The second graph (attachment 2) to which I would like to draw your attention depicts the variations we have found in the probability of death following bypass surgery. The graph reveals that the relative risk of a Medicare beneficiary dying over a two-year period following this procedure varies across States. At this very early point, the data suggests that the difference in relative risk is real for only some of these States. We do not have sufficient data yet to be confident that the differences are real for all of the States, but we are pursuing the matter.

Allow me to caution you at this point that our investigations on the reasons for these differences are just beginning. However, I think these findings give you a flavor for the type of research we are pursuing.

Dissemination

Perhaps the most important element in our effectiveness agenda is how we plan to use the information we generate. It is critical that the information generated be shared with the medical practitioners who recommend treatment alternatives and the patients whose lives are affected by them. After all, information is valuable only when the people who need it have it and are able to act on it. Practicing physicians are a vital link in this initiative. We believe they must be involved in all aspects of the effort including determining the right questions to study, the data elements necessary for research, and how the results will be presented to the medical community. We look forward to their continued support.

Sharing information with the public is a goal that we strongly advocate. We believe that the government has a responsibility to provide information to the public about health services because it is a "public good", the benefits of which accrue to everyone. For example, once again HCFA plans to release hospital mortality information in December. We have worked hard to make the information more valuable by designing a tool for hospitals to use in adjusting for the severity of patient illness at each hospital.

We also believe that an informed consumer is better able to make appropriate choices regarding health care. We will begin targeting information to consumers later this year when we release information on the quality of nursing home care. This information will be based on facility inspections and will include such indicators of quality as good patient nutrition, infection control, and proper medical care. As with the hospital mortality information release, we are working closely with experts in the field, consumer groups, and medical practitioners to provide this information in a meaningful format. Ultimately, our goal is to make necessary information available to consumers and the health care community on the quality of care provided in institutions and on what types of medical treatments are proven clinically effective.

Public/Private Sector Coordination

HCFA's effectiveness initiative must begin with the identification of problems and opportunities for further investigation. To help us set priorities for this effort, we are working with the American Medical Association and the Institute of Medicine as well as a number of nationally prominent clinicians to identify those basic areas of medicine where there is particular uncertainty. We expect the group to gather this summer.

Once priorities have been established, a second panel of experts identified through the AMA and other physician groups will help us choose specific conditions, procedures, or technologies to be evaluated. We hope to convene this group in early Fall. These and other interactions with the physician community will help us develop our research priorities.

In effectiveness research, we have before us an opportunity to enhance the quality of care rendered not only to Medicare beneficiaries, but to all patients. It is our view that the issue of effectiveness of health services is one in which there should be a unity of purpose; everyone should support developing better information as a means to better health care.

In order to raise awareness and focus direction in effectiveness research, we plan to continue building consensus with other concerned parties including members of the medical community, researchers, educators, consumer advocates, private purchasers of health services, policy makers, and health care managers. We have consulted extensively with all of these groups as our Effectiveness Initiative has evolved. Last month for example, HCFA assembled representatives of these groups to address the issues surrounding effectiveness research, including the appropriate role of government, data requirements for research, and funding. This meeting confirmed our inclination that HCFA, by virtue of its role as a purchaser of health services, researcher, beneficiary guardian, and educator is in a unique position to take a leadership role in facilitating this important work.

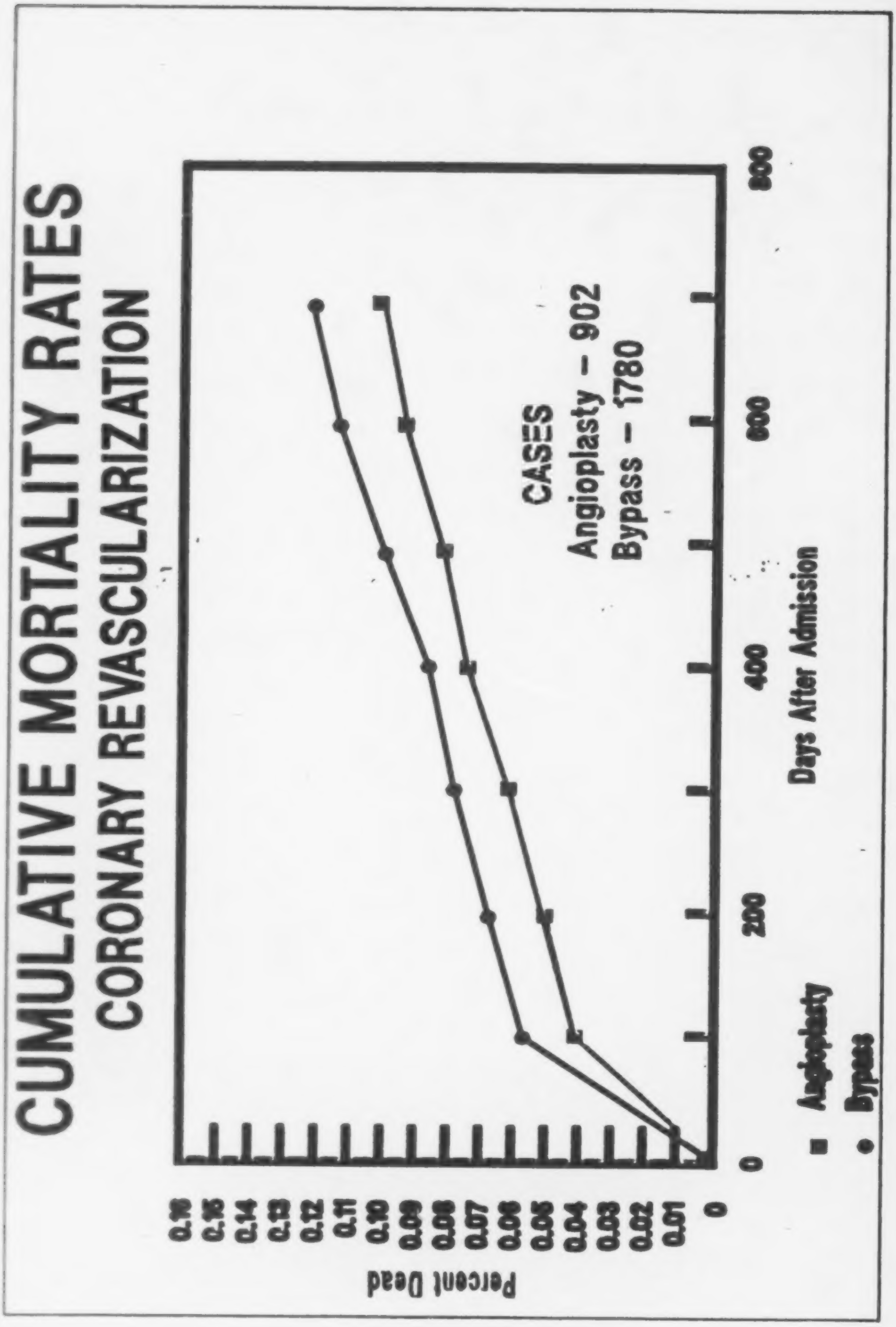
Conclusion

Through the Department's Effectiveness Initiative, we are embarking on a major change in both the role of government in health care and the practice of medicine by physicians. And, Mr. Chairman, as I am sure you know, physicians in the State of Maine have already begun exploring some of these issues. The Maine Medical Assessment Program (MMAP), sponsored by the Maine Medical Association, monitors information on practice variations among Maine communities and communicates it back to physicians through group discussion meetings. We are pleased that such efforts are being conducted locally, and we believe that our efforts on the national level will complement these types of activities by adding measures of the outcome to the discussion of which utilization pattern is preferable.

The Effectiveness Initiative has significant potential to improve medical care, but it will require the cooperation and support of the very diverse groups involved. The Initiative requires effort, but the benefits we expect will far outweigh the effort. Having better information concerning the relative benefits of various treatment options will allow physicians to make better clinical decisions and give patients the opportunity to be more involved in those decisions; give payers better information on what they are paying for; aid health services managers make better decisions concerning resource allocation and new technology; increase competition based on evidence of quality; and perhaps even provide protection for physicians against frivolous malpractice suits.

Before I conclude my statement, allow me to point to one final graph (attachment 3), which I think will help in conceptualizing the goal of our Effectiveness Initiative. As the graph illustrates, we believe that our efforts will move medical care in a positive direction toward a higher level of quality. I suspect that there will always be a few providers rendering poor quality care regardless of the information available to them -- and that's why we need to maintain a strong commitment to our more traditional quality mechanisms -- and there will always be some providers who go beyond what we, as a society, demand of them. Most providers will remain somewhere in the middle, striving to provide high quality care within the means available to them. The goal of our initiative is to help move the entire curve of providers into a new range of quality. This initiative is not a "quick fix": research is costly and time-consuming. We will need the support of Congress, and all those involved, and we look forward to keeping you informed of our results.

I would be pleased to answer any questions you may have.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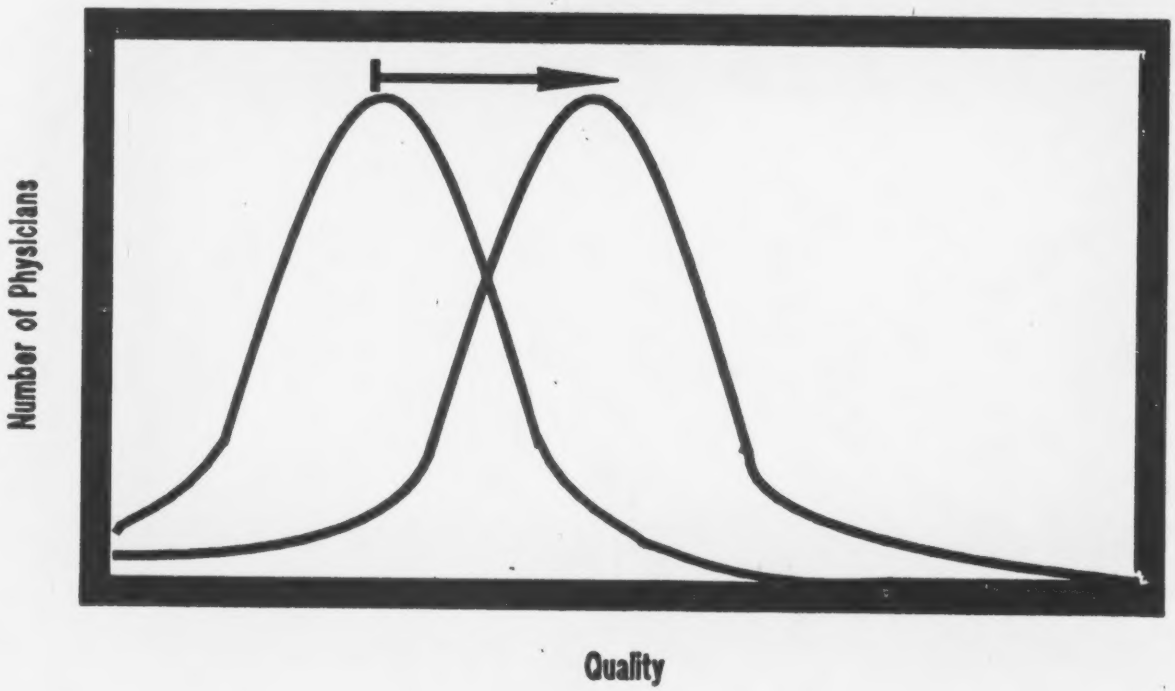
IMPROVING THE QUALITY OF CARE



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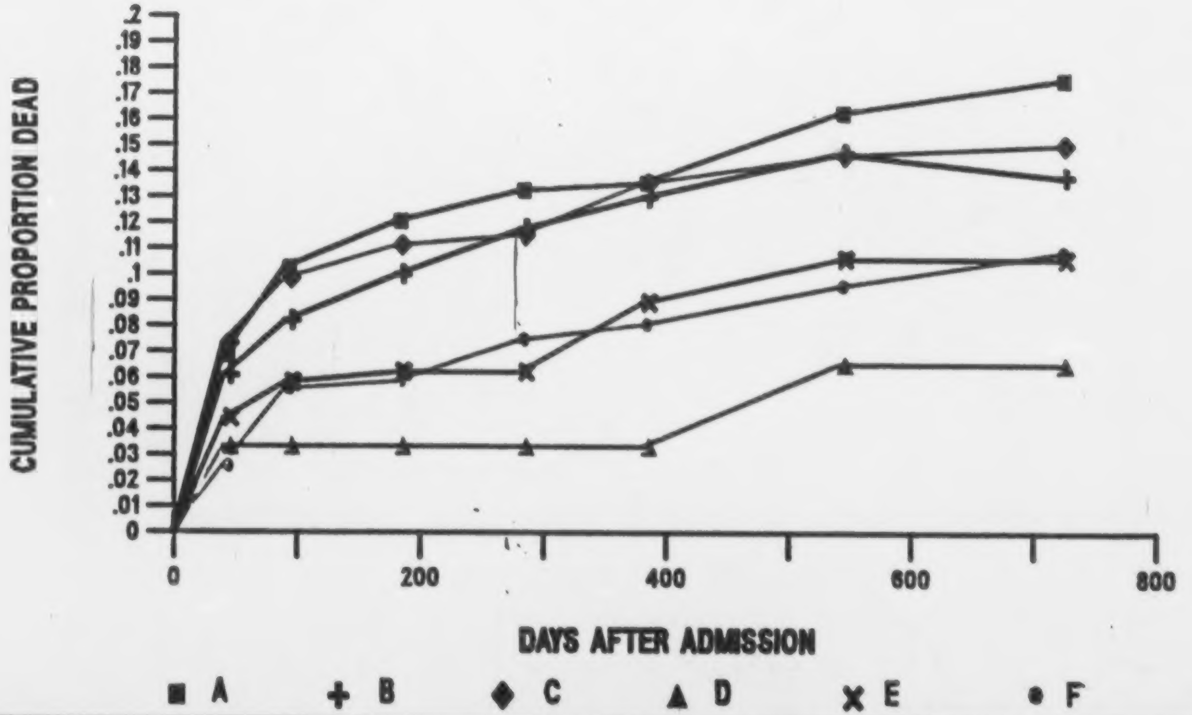

RESPONSES OF DR. ROPER TO QUESTIONS FROM SENATOR HEINZ

Q. Explain how HCFA's "effectiveness" initiative will address:

1) **the development of a data base that can be used to assess physician services in ambulatory care centers, physicians offices, and HMOs;**
2) **the development of measures that can rate hospital "morbidity" rather than just "mortality" factors; and**
3) **research on the impact of alternative payment approaches (such as relative value scales) on physician practice and utilization patterns.**

A. 1) The Health Care Financing Administration is currently developing a Uniform Clinical Data Base to permit more adequate assessment of inpatient care. A corresponding Uniform Ambulatory Care Encounter Record will be developed to assess the effectiveness of services in physician offices, HMOs, and other ambulatory care settings. Beginning in April 1989, the claim form we currently use for ambulatory services (HCFA Form 1500) will be amended to capture diagnostic as well as procedure information. In addition, we hope to add a section to the form which will describe the patient's functional status, thereby allowing us to track a patient's health status over time. Collecting these additional pieces of information at each ambulatory care visit will give us more information with which to conduct effectiveness research in outpatient settings.

The information compiled on the Uniform Ambulatory Care Encounter Record can be used to assess the effectiveness of ambulatory care when it is linked to the patient's subsequent ambulatory and/or inpatient care records. The data may also be linked to specific outcome measures, such as mortality. Our goal is to use such information to assess the health status of Medicare beneficiaries and the outcomes of various medical interventions.

2) While the assessment of mortality trends in the Medicare population is an important objective in our effectiveness initiative, we also plan to study other outcome measures including morbidity, disability, and cost of care. We define "morbidity" as the deterioration of health to the point of requiring medical intervention, either in an inpatient or outpatient setting. We plan to assess morbidity by linking the many kinds of information contained in the enormous Medicare claims data base. It is HCFA's intention to assess, as broadly as possible, the consequences of various medical interventions, and make the results available to the people who need it most -- physicians and patients.

3) The goal of HCFA's effectiveness initiative is to develop sound information concerning which practices, services, and procedures work best for particular cases. HCFA does not pay for care known to be ineffective. Newly-developed information concerning effectiveness of care is routinely factored into Medicare coverage policies for specific services and procedures performed by physicians.

Presently, there is a dearth of scientifically-based information about the effectiveness of medical practice to incorporate into existing projects addressing alternative payment approaches (such as relative value scales). Studies of the behavioral responses of physicians to the effectiveness initiative -- as reflected by changes in their practices, pricing, and/or utilization -- are a high priority in current and planned projects.

Q. How will research on physician practice patterns in non-hospital settings be incorporated into PRO pilot studies on the quality of physician care in ambulatory settings due to begin January 1989? What is the status of HCFA's preparations for these pilot studies?

A. The pilot projects are designed to address the continuum of patient care, rather than isolated episodes of care. We plan to gather information on the services rendered (procedures), the conditions requiring these services (diagnoses), and the functional state of the patient at the time of the encounter. The quality of care will be measured by its effectiveness, i.e., its impact on mortality, morbidity, disability, and expenditures. The pilot projects to develop and test these concepts are being designed at present. Formal implementation plans will be developed this fall.

Q. Last year, OMB and Senate Finance Committee Members reached an agreement that substantially increased HCFA's budget for quality assurance. What level of resources do you believe are needed to support HCFA and Congressional priorities over the next two years? What level would be needed to also cover improvements in mortality methods, and other priorities listed in the previous question?

A. Most of the increased cost of our quality assurance efforts result from Congressionally mandated expansions of Peer Review Organization (PRO) activities. The budget calls for PRO funding of $321 million in FY 1989, which represents a 70 percent increase over the FY 1988 level. This figure also includes $11 million to fund various pilot projects, including the review of outpatient physicians services referred to in the previous question. In addition, $67.3 million will be spent in FY 1989 to survey hospitals, skilled nursing facilities, hospices, End Stage Renal Disease facilities, and independent laboratories to certify that they comply with Medicare standards and conditions of participation.

For FY 1989, 17 percent of HCFA's $50.5 million research budget is devoted to activities surrounding quality of care and effectiveness of medical practice. Also for FY 1989, $5.9 million in Medicare trust fund monies will be transferred to the National Center for health Services Research (NCHSR) to conduct patient outcome assessment research.

Q. If we are to be successful in the development and application of patient outcome research, those who will be directly affected (providers and consumers) will need to be assured that the process and products are not politically biased or scientifically/medically unsound.

With this as a goal, what do you believe are the appropriate roles for government agencies (NCHSR, HCFA, NIH, CDC, and others), providers, researchers, and consumers in the scientific research and application phases of patient outcome data? For example, who should do the basic research; develop standards of physician practice; collect, analyze and disseminate data; and validate data accuracy?

A. Improved information on the effectiveness of health services is of interest to everyone involved in health care whether they be payor, provider, or consumer. While the private sector has, and will continue to contribute to our knowledge in this area, the market system may not assure that adequate investment is made in the research and data collection necessary to improve information in this area. The government has a historic role in providing information that is considered a "public good", particularly in the health care arena.

The primary reason that HCFA, in particular, has actively pursued its effectiveness agenda is two-fold: our commitment to quality care for Medicare and Medicaid beneficiaries and the availability of a unique national data base that can be used to compare alternate treatments for a wide range of patient conditions.

While HCFA sees itself as a key player in effectiveness research, we consider the initiative an inclusive undertaking. We are presently working with NCHSR, the National Cancer Institute, and Center for Disease Control to pool information, funds, and data on specific research projects. We are formulating a joint agenda for future research with NCHSR and other components of the Department.

We are also pursuing joint efforts with entities outside the Department. We have announced an initiative to make Medicare data available to effectiveness researchers. We are pursuing joint efforts with other third party payors to pool our data to permit more comprehensive analyses. And, we are exploring joint ventures with the physician and provider communities.

Statement of the

American Association of Retired Persons

by

Eva Skinner

Member, AARP Board of Directors

July 11, 988

Good afternoon Mr. Chairman. My name is Eva Skinner and I am a member of the AARP Board of Directors. I am also privileged to serve on the Board of Directors of California Medical Review, Inc., the PRO for California. As a registered nurse and Medicare beneficiary I have both a professional and personal interest in the outcome of medical services provided under Medicare.

Thank you, Mr. Chairman, for this opportunity to state the Association's views on an area of health care research that is long overdue: patient outcome assessment. It is surprising to most lay people that the efficacy of medical treatments, relative to a particular patient in a specific situation, is not known. That we are nearing the end of this century and know very little about the outcomes of medical treatments and procedures prescribed and performed on a routine basis day after day is disturbing.

Nonetheless, AARP is encouraged by the growing level of attention and resources being devoted to understanding the outcomes of medical interventions. In an era of severe cost restraint, patient outcome research is crucial to protecting patients and to manifesting the basic societal values concerning access to appropriate medical care.

My primary message today is that we strongly support increased research aimed at outcome assessment. At the same time, because the current state of outcome research is in its infancy, we must caution against linking initial research findings to payment decisions.

My testimony focuses on three areas:

1. Setting a Context for Outcomes Research;
2. Research Priorities; and,
3. Recommended Uses for Outcomes Research.

SETTING A CONTEXT FOR OUTCOMES RESEARCH

Rising health care costs will continue to be a major concern for Americans of all ages. What must not be lost in the effort to achieve a more efficient, balanced system, is access to a quality medical product across the entire continuum of service needs. But the threshold challenge is to better understand what quality medical care is so that the provider/patient relationship and the incentives in the payment schemes support widely available, quality medical care.

Consumers faced with a tightening of health care resources and consequent cutbacks in care are questioning, and rightly so, just what it is they are buying for their health care dollars. AARP envisions the development and implementation of a quality assessment and assurance system that (1)identifies problems in a timely way, (2)implements appropriate corrective actions, (3)monitors the effectiveness of the actions taken, (4)yields data that can be used by researchers to evaluate the "product" being delivered by the system, and (5)generates quality of care information to the provider and consumer communities. Such a system does not yet exist in its entirety. Pieces of it are in place, however, and we must continue to move towards its full realization.

AARP agrees in principle that reductions in medical care based upon the application of appropriate medical criteria are a worthwhile goal in terms of seeking both reduced cost outlays and improved health outcomes. We say, yes, reduce truly unnecessary surgery and avoidable deaths and truly unnecessary hospital days. But AARP remains concerned that we are experiencing a stampede towards reductions in health care delivery. Everywhere we look, insurers, review organizations, and new health delivery systems are touting their ability to reduce utilization through the magic of "managed care."

While AARP acknowledges and supports the effort to contain health cost inflation, health delivery decisions should emanate primarily from a commitment to quality assurance and not merely to cost containment. The Association has long held the view that shorter lengths of stay do not necessarily imply inappropriate care. By the same token, high quality care is not necessarily more expensive care; insuring good outcomes by delivering all necessary and appropriate services may, in the long run, save precious health care dollars.

AARP seeks a strategy that truly improves health outcomes while respecting the physician-patient bonds that attend the healing process. AARP's interests lie in maintaining an efficient, cost effective health care system that at the same time remains humane, caring, and capable of renewing the trust and mutual respect between doctor and patient that is an integral part to patients' recovery from illness.

In this connection, we must not lose sight of one aspect of the issue of appropriateness, namely, the question of where and under what conditions an appropriate health care service should be performed. In the enthusiasm for reducing unnecessary hospital admissions, many Medicare beneficiaries who formerly would have been treated on an inpatient basis, are now being required to receive surgical and other procedures as outpatients. While this is appropriate in some instances, there are numerous situations in which outpatient treatment carries a potential risk because of factors specific to the particular patient. Generalized conclusions about outcomes must not override the particular needs of an individual patient.

RESEARCH PRIORITIES

Data is Central: The Association believes there is much to be done before patient outcome assessment research will provide the kind of information upon which basic policy decisions can be made. As recognized by the Government Accounting Office (GAO) and others, the information routinely collected by the Health Care Financing Administration (HCFA) and their contractors is not amenable to the task at hand. Patient outcome assessment requires information that can trace a patient's progress through the entire spectrum of care; from the ambulatory setting of their physician's office, through a hospital stay, to post-acute care services and, hopefully, recovery.

However, despite the collection of information about each component of such an episode of illness, HCFA cannot combine the various databases involved to produce a longitudinal description of a particular patient's care. Absent such a longitudinal picture, it is impossible to assess the outcome of patient care and relate the outcome to appropriate changes in public policy.

A necessary prerequisite to assessing patient outcomes is thus the development of an information system that describes an entire episode of illness, not just an isolated component of it. In this connection, HCFA's efforts to link Parts A and B data must proceed as a high priority project. Physicians must be required to include uniformly-coded diagnosis data on Part B claims. Such information is important to the measuring and monitoring of quality in various settings of care. Moreover, high priority must be given to the development of patient-oriented quality assessment in post-hospital care, such as skilled nursing facilities (SNFs) and home health care.

Constructing such a data-based quality assessment and assurance system will require much greater coordination among the HCFA contractors administering Medicare. Intermediaries, carriers, and PROs must begin to collect and process basic data elements in a uniform way to assure comparability among providers. Standardization of quality of care measures and methodologies will give greater assurance to beneficiaries about the quality of their medical care and lead to nationally representative information.

The information collected by this quality assessment and assurance system should serve as the basis for a national epidemiological data base of relevant patient-level data on the overall quality of care to Medicare patients, regardless of the setting of care. Such a data base will be an invaluable tool for assessing beneficiaries' access to the various levels of care and lead to a greater understanding of the ways in which quality affects beneficiaries' health status and quality of life.

Small Area Variation Studies: Key to assessing the outcomes of patients' care is understanding the variations in patient care. Research has consistently shown that there is wide variation in the use of health care service among communities that are seemingly the same. Large variations in hospital admissions and discharges, lengths of stay, patient days, and per capita expenditures have been documented. In addition, huge variation in the use of surgery has been routinely documented. Researchers are beginning to find even greater variation in medical diagnoses than was found in surgical procedures.

These variations in the use of health care services from community to community raise basic questions about the outcome of patient care. Patient outcome assessment research must begin to account for these variations if patient outcomes are to play any role in developing policies concerning the need for care, the site of care, or payment for care.

Given the documentation of wide variations in hospital use, research must be undertaken to determine the effect such variations have on the outcome of care for individual patients and the health status of a specific community. Studies should be initiated to (1) determine the clinical and functional implications of variation, including the refinement of measures of both health and functional status; (2) better understand the need for medical care and the demand for medical care and the outcomes of each; (3) assess outcomes in terms of health status, measured at various times following medical intervention; (4) assess the extent to which variations in the length of stay affects outcome; and (5) determine whether the site of providing care affects the outcome of care.

The Role of Peer Review Organizations: The Association has long believed that Peer Review Organizations have a central role in the development of the health care quality assurance system for this country. PROs should be in the forefront of quality assurance research because they represent the Nation's commitment to quality in medical care; a strategy of both strengthening PROs and holding them increasingly accountable is obviously in the public interest.

The recent onset of a national small area variation study managed by the American Medical Review Research Center is particularly noteworthy. PROs will have an important role in organizing the physician community to help explain the emerging data and make judgments about what it means for both the costs and quality of medical care.

RECOMMENDED USES FOR OUTCOME RESEARCH

A Caution on Linkage to Reimbursement: The fruits of outcome research have powerful implications for both the cost and quality of health care services in the United States. While the Association envisions a range of appropriate uses for such information over time, for the foreseeable future, AARP emphasizes caution in using conclusions drawn from outcome research for purposes of reimbursement. Our limited knowledge and understanding of the subtle complexities inherent in the healing process makes such use of outcome research hazardous for Medicare patients at this time. The current, wholesale relegation of certain surgical procedures under Medicare to the outpatient setting, despite the needs of individual patients, is ample evidence of the harm that can be done by linking payment decisions to inflexible generalizations about what is appropriate care.

Moreover, premature use of outcome data for purposes of reimbursement could jeopardize broad-based professional support and involvement in the dynamic process of assessing and explaining the outcomes of various medical intervention. Professional involvement and commitment to understanding the medical efficacy (as opposed to the financial efficacy) of the outcomes of treatment under various circumstances is crucial to understanding what appropriate care is.

Meanwhile, the difficulties inherent in attempting to judge appropriateness of care continually reappear. Certainly in recent years there has been no more derisive reference to treatment deemed unnecessary than the often-pointed to use of vitamin B12 shots. Now comes the prestigious New England Journal of Medicine with its June 30 report of a possible link between low levels of vitamin B12 and a wide variety of neurologic disorders. "Could it be," editorialized Massachusetts General Hospital physician William Beck, "that many (vitamin B12) injections given over the years for vague symptoms were in fact justified?"

Outcomes Research and Consumer Choice: The translation of outcomes data into information to aid consumers in making more informed health care choices should be a long-term goal of the research efforts being discussed today. A better-informed patient will enhance the physician-patient discussion of treatment.

Public disclosure of comprehensive, analyzed and uniform outcome data can yield two positive results: 1) a more informed patient community better able to discuss health care choices with providers and 2) a new health system dynamic that will lead health care providers to compete on the basis of quality. The debate about data disclosure has shifted from a focus on whether information should be published at all, to how to release data so consumers can use it effectively. We must rise to the challenge of turning raw statistics into a picture patients can understand.

AARP expects to see a variety of process of care and outcomes of care measures developed and reported to the public on a routine basis. Such data will certainly be useful to consumers as a basis for questioning medical professionals about the significance it may have in a particular patient's case. In addition, the disclosure of outcomes data on Medicare patients should also help generate a constructive dialogue between providers and consumers of health care on what constitutes quality of care, and how best to measure it; in the process, society's expectations of health care encounters will likely become more realistic. The best way to align society's expectations of medicine more closely with clinical performance, is to provide more information, presented in an understandable way to the public.

In a broader and perhaps more philosophical vein, what we are positing here is a vision of consumer choice that fulfills the hopes and goals of those who have sought to foster patient autonomy in the interaction of patient and health care system. Those who have waged the long battle against the paternalism of providers in the interest of a healthier relationship are not ready to quietly accede to a new paternalism of payers or corporate purchasers based upon unilateral declarations of what is or is not "effective" treatment.

Thank you again, Mr. Chairman, for the opportunity to present AARP's views on this very important issue. I would be pleased to try and answer any questions you or the committee might ask of me.

PREPARED STATEMENT OF ANDREW WEBBER

Mr. Chairman, I am Andrew Webber, Executive Vice President of the American Medical Peer Review Association (AMPRA). AMPRA, is the national association of physician directed medical review organizations, including the federally designated Peer Review Organizations (PROs). AMPRA members conduct medical reviews of health care services provided to beneficiaries of the Medicare and Medicaid programs and to individuals in health plans which have contracted for these services privately. I am accompanied today by Robert Weiser, Executive Director of KePRO, the PRO for the state of Pennsylvania.

We are particularly pleased to have this opportunity to testify on patient outcome assessment research as our Association has long advocated the need for empirically-based measures of health care quality. For this reason, Mr. Chairman, AMPRA supports S.2182 the bill that you have introduced to financially support medical outcome research. While important steps have been taken to reform Medicare payment for hospital services and to encourage Medicare beneficiary enrollment in capitated health plans, we have made only limited progress in assuring that quality health care services are appropriately rewarded. Most payment reform initiatives to date seek to create financial incentives for the economical provision of care. Such incentives are clearly powerful, but we do not know as yet what their long-term effects on the quality of care will be. S.2182 represents an important first step in better understanding the results of medical treatment and linking patient outcomes to clinical performance.

Our Association believes that provider payments should be guided by the principle of economic reward based on quality performance. Whether our policies become more regulatory or more market oriented, the incentives should encourage excellence in provider performance. In order to design and implement such an incentive structure it is necessary to develop more explicit definitions of quality and improved techniques for measuring it.

Today's hearing is an important opportunity for us to take stock of where we are in the science of measuring and monitoring quality, and to consider ways to coordinate and focus efforts that are currently underway to advance our knowledge in this critical field. All of us recognize that resources for health care delivery are scarce, and the pressure to continue doing more with less is not likely to abate in the near future. It is precisely because of the cost containment imperative that we must become more skilled in measuring and monitoring quality in health care delivery.

As observers of the health care system, all of us are acutely aware of the great variety that exists in the provision of care. In fact we celebrate this variety as contributing to the climate of creativity that has produced such progress in medical science in the United States. Of course we pay a considerable price as a result of this diversity. We believe that the time has come for us to begin in earnest the task of integrating our knowledge about health care interventions, so that we may begin to narrow, where appropriate, the range of medical practice.

The Need for Quality Assessment

There is a great deal of money being spent to assure quality of care through mandating the existence of certain structures and processes in organized health care delivery systems. Hospitals are subject to licensure and accreditation standards which rely on building codes, committee structures, appropriate bylaws and other procedures. Health professionals are licensed and granted admission privileges based on educational credentials and examination scores.

We have repeatedly learned that strict adherence to all of these standards and regulations does not assure the maintenance of quality. We need to know what ultimately happens to the patients who traverse the health care system. Are they better or worse at the end of their encounter with organized health delivery, and can we identify those patterns of practice that should be promoted and those which should be questioned. To answer these questions we must have a standard for acceptable outcomes to medical intervention, and we must be able to distinguish the impact of treatment from other factors beyond the control or knowledge of the practitioner. To accomplish this most difficult task, we must rely on the following assessment tools.

An Integrated Data Base

Mr. Chairman, despite all the information that we are presently collecting from our health care system, we do not have an integrated data base with objective clinical indicators and with information about the diagnostic and therapeutic interventions in ambulatory, acute and post-acute care settings. What data we do have is generally limited to one setting (e.g. inpatient hospital) or one payer (e.g. Medicare), and is not comparable.

The foundation for epidemiologic study is the ability to track both the utilization and outcome of medical care services across all settings. We simply cannot do that with respect to most patients in our delivery system. Without such a data base, outcome assessment cannot move from a limited experimental base to become an important tool for quality assurance.

Significant investments are needed to reach agreement on a uniform clinical data set and to integrate and expand existing data bases. Working with the Health Care Financing Administration (HCFA) we are participating in a task force to identify the types of patient information necessary for outcome assessments and medical review and to explore the feasibility of standardizing clinical data needed for PRO review activities. While this is a critical first step, additional efforts must be mounted to assure that we have comparable and timely clinical data on all patients.

We also need to expand the type of clinical information collected to include not only physiological data, but also objective measures of patient functional status which is particularly important for those patients with chronic diseases. We could then begin to group patients according to the severity of their conditions facilitating more appropriate comparisons of patient outcomes. We believe this information should be collected as a condition of payment to assure its timeliness and universal compliance. Apart from enhancing the quality assurance function, better and more complete clinical data would permit provider payment systems to more adequately recognize and pay for differences in patient severity of illness. We do have a concern that much of the work on measuring severity of illness is being carried out by proprietary firms limiting the use of such tools to those able to purchase the systems.

Longitudinal Outcome Studies

Another important objective in efforts to assure quality in our health care system is the conduct of longitudinal outcome studies. There is no substitute for well-funded clinical trials to evaluate the efficacy of alternative treatment protocols. Clinical decision-making is too often plagued by uncertainty and provider preference because carefully controlled trials have not been conducted to assess patient outcomes. Longitudinal outcome studies are needed to decide questions of medical efficacy and to assure both quality and cost-effectiveness.

Practice Guidelines

Finally, we want to call your attention to the need for work to establish better clinical guidelines and practice standards. Ideally, the results of outcome research can be fed back to the practitioner and form the basis for more informed individual judgements by practitioners, and, where appropriate, for the establishment of clinical guidelines. AMPRA would like to recognize the important contribution of the Rand Corporation in beginning to publish indicators for treatment that have been developed through a concensus process involving practitioners and clinical researchers. Yet, much more work needs to be done. Medical specialty groups, in particular, need to broaden these efforts. AMPRA believes that better information on outcomes made available to all practitioners, plus explicit clinical standards in certain areas, developed through an appropriate consensus process, will result in more effective and economical health care for all our citizens.

We recognize that this is a controversial area and we are aware of the concerns of many in the medical profession about the risks of mandating medical practice standards. Such guidelines used indiscriminately by third party payers could inappropriately interfere with the judgement of the practitioner in the care of his or her patient. That is why AMPRA firmly believes that clinical guidelines that have the potential to affect payment decisions should be applied under the direction of local physician based review organizations.

The application of more explicit clinical standards must be accompanied by sensible medical judgements that, on an individual basis, take account of unique patient characteristics, knowledge of the local care resources, and the social needs of the patient. In short, physicians must always maintain the flexibility to deviate from the guidelines when their best medical judgement dictates a different course of action. This freedom cannot be limited by arbitrary and uniform application of even the best clinical standards.

In attempting to describe the need for quality assessment in our health care system, we have identified the requisites for further progress in this field:

- an integrated clinical data base covering all health care settings;
- the expansion and refinement of the patient information required for quality assessment;

- the conduct of clinical trials and other outcome studies to enrich the research base for practice; and

- the development of clinical guidelines and standards of practice through the collaboration of researchers and practitioners.

The Role of PROs

AMPRA strongly believes that Peer Review Organizations should serve as effective change agents for influencing medical practice. We have witnessed time and again the power of PROs as educators, presenting information about the practice patterns of physicians at the local level. As progress is made in the areas outlined above, PROs can be the agents for communicating additional information and practice guidelines to busy clinicians.

By way of illustration, twelve PROs are presently participating in a HCFA-funded research project applying the population-based methodology of small area analysis to Medicare data nationwide, with the results reported to physicians through educational programs.

This project is one of several stimulated by congressional directives to improve methods for evaluating the utilization, cost, and quality of medical care provided to Medicare beneficiaries.

Under the project, utilization rates will be calculated for every medical and surgical condition by DRG, as well as readmission and mortality rates. Computer programs will be developed to display local variations showing physicians how their practice patterns compare with those of their peers. Among the project objectives is the use of PROs for the conduct of an intensive educational program consisting of review, interpretation, and feedback of information to physicians on identified practice patterns.

In many ways this project builds on activities underway since the inception of the PRO program. The development of review criteria and standards, the identification of PRO objectives, and the outreach programs of PROs, all seek to bring valid and objective data to the physician as a practical tool for the conduct of their practice. We believe all these efforts are a part of the consensus building process that over time will reduce appropriate variability in physician practice.

PROs should also play a role in validating research findings through their own experience in evaluating care. The relationship between PROs and the research community must be an interactive one through confirmation or revision of research results.

At the same time, PROs can help assure that research conclusions are made operational by their use in establishing review criteria and standards, and by helping to disseminate the results to the medical community.

In this latter role, PROs are beginning to explore the use of computer-based systems for screening cases for physician review. Much of that work is presently done manually by non-physician reviewers. The objective is to build into a computer program a series of clinical algorithms, input the abstracted clinical data, and identify those cases which require physician review because they are not consistent with the clinical models. It is hoped such an approach could increase the efficiency of the screening process and reduce the volume of physician reviews.

In sum, we believe that PROs play a vital role not only in conducting their quality assurance functions, but in their capacity to translate the findings of research into practical guidelines for the practicing physician. We have always felt that these activities were much more significant than the number of Medicare cases denied for payment, or the number of practitioners recommended for some type of program sanction.

Outcome Research Priorities

At the risk of raising what has become an unpopular topic, we feel strongly that the financial support of the federal government should be increased to support both outcome research and the use of outcome research findings to affect behavior changes in the practitioner community.

The two and one-half year project described earlier, applying small area analysis techniques to Medicare data and using selected PROs for the dissemination of the findings, is a very modest undertaking.

These projects are expensive and certainly they should not be the exclusive responsibility of Medicare. However, we believe that there should be a federal focus for these efforts to assure coordination of projects. There is also a great need to operationalize the research findings and the results of technology assessments so that they can be applied in the quality assessment and outcome measurement process.

For these reasons, AMPRA strongly supports S.2182 that authorizes a specific budget for these purposes on an annual basis, to be administered by a designated agency, and involving competitive awards for the conduct of necessary projects to advance outcome assessment in health care. In the aggregate the Medicare program now spends a very limited amount of money for these purposes.

Within the PRO program we have also recommended that Congress authorize a quality of care research and education center for the purpose of further developing the art and science of quality review. Such a center could, for example, help PROs improve their performance, test out new review methodologies, conduct studies of PRO activities, and help to identify appropriate uses for mortality and morbidity data.

AMPRA, together with its research affiliate, the American Medical Review Research Center (AMRRC), stands ready to play a larger role in these areas if sufficient resources are made available.

Mr Chairman, AMPRA believes that these efforts represent an effective strategy for the containment of medical care costs while improving the quality of care.

It involves a concerted, systematic effort to increase medical professional consensus about whether, when and how to treat. Evidence of wide variations in practice patterns highlight differences of opinion within the profession concerning the appropriateness of treatment alternatives.

If research and peer review efforts result in more conservative medical practice, health care expenditures could be reduced with improved quality. However, it should be understood that in some communities more service, not less, is needed. Nevertheless, narrowing the tremendous range in practice through building greater medical consensus holds the promise of forestalling stricter regulatory control, and avoiding arbitrary rationing of care.

Again, we want to thank you for this opportunity to address this critical public policy concern. We look forward to working with you in the development of additional support to carry out the important work that remains to be accomplished in the assessment and monitoring of quality in the health care delivery system. We would be pleased to answer any questions you or other members of the Subcommittee may have.

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I am pleased to testify in support of S.2182, a bill to increase the authorized appropriation for the Patient Outcome Assessment Research Program. The thalidomide tragedy of the 1960's galvanized this nation's determination to test the efficacy of drugs, but we have neglected the equally important need to apply the ethic of evaluation to the use of hospitals, surgery, diagnostic tests and other treatments physicians use routinely in their practices. As a result, there is a double standard for truth that compromises the scientific basis for decision making in clinical medicine. S.2182 seeks to remove the double standard by expanding the mandate to evaluate health care outcomes to include the full spectrum of treatments physicians use, but it does so without resorting to regulation, a strategy that I believe would bring failure to the effort. It authorizes the National Center for Health Services Research and Health Care Technology Assessment ("The National Center") to fund projects to evaluate the various options available to physicians in the treatment of a given condition.

Examples of Assessment Problems the Program Addresses

The implementation of S.2182 will provide answers to a number of unresolved clinical hypotheses which, left unexamined, compromise the rationality of clinical medicine and reduce the status of physicians and the confidence of patients. For example:

The last few years have seen the rapid proliferation of medical theories concerning the best way to treat chest pain caused by impeded blood flow in the artery that feeds the muscle of the heart. Some physicians recommend surgery--the well-known coronary bypass operation. Others recommend coronary artery angioplasty--the insertion of a balloon catheter into the heart's artery which is then expanded to reduce the obstruction. Still others recommend drug treatment. Debates about the relative value of these different treatments rage in clinical medicine, but because the outcomes are not systematically compared, the debates cannot be settled. The National Center's Outcome Assessment Program is designed to undertake the systematic evaluations need to test alternative strategies for treating this common clinical problem.

There are new ways to treat arthritis of the hip and knee. One approach involves the surgical replacement of the hip or knee joint and for physicians and patients who choose this method there are a number of alternative ways of accomplishing the replacement. There are many choices but no consensus on which approach is best for the patient. There is also considerable disagreement about when in the natural history of the disease the operation should be planned if at all. These differences in opinion translate into costly differences in the rates at which various services are performed in different parts of the country. The National Center's Outcome Assessment Program is designed to develop the scientific information needed to settle these controversies.

The evaluation of the outcomes of clinically different approaches to treating common medical conditions such as back pain, pneumonia and gastrointestinal disease is perhaps the most neglected area of all. In many communities in this country, physicians favor the outpatient setting for treating these patients, while in other communities the standards of practice favor the use of hospitals. Similar uncertainties and controversies about correct practice exist concerning the value of intensive care units. The National Center's Outcome Assessment program is organized to target these expensive uncertainties.

The Consequences of the Double Standard for Truth

Neglect of these and a host of similar uncertainties and controversies about the scientifically and ethically correct way to practice medicine has enormous consequences for patient well-being and for the health care economy. Unresolved discrepancies in medical theory are responsible for much of the practice-style-driven influences on demand that affects the cost and use of care, even in medically sophisticated communities. Consider Boston and New Haven, which are renowned centers of academic excellence in medicine. The residents of these two communities are remarkably similar in demographic characteristics that predict the need for care. They receive virtually all of their medical care from physicians affiliated with some of the nation's finest medical schools. By definition, the medicine in these communities must be viewed as state of the art. But how different is the state of the art of medical thinking in these two communities, viewed from the perspective of what happens to patients:

> Residents of New Haven are about twice as likely to undergo a bypass operation for coronary artery disease as their counterparts in Boston who are more likely to be treated by other means. On the other hand, Bostonians are much more likely to have their hips and knees replaced by a surgical prosthesis than are New Havenites whose physicians tend to prescribe medical treatment for these conditions. Bostonians are more than twice as likely to have a carotid endarterectomy--the controversial operation undertaken on the theory that it is the best way to prevent strokes arising from disease of the artery in the neck--while clinicians in New Haven appear to prefer medical management involving the daily use of aspirin or other drug. By contrast, hysterectomies for non-cancerous conditions of the uterus are more commonly performed on New Havenites.
>
> Most significant for the costs of medical care, Bostonians are much more likely to be hospitalized for medical conditions than are their counterparts who live in New Haven. In 1982, Medicare reimbursements for hospitals were $1,894 in Boston per person, while in New Haven they were $1,078. If New Haven reimbursements had applied to the 78,000 enrollees living in Boston, the outlays would have been $63 million less--$85 million rather than the actual $148 million. Decisions on the best place to treat a host of acute and chronic medical conditions--the most common and costly examples of the differences are the treatment of low back pain, pneumonia and gastroenteritis--accounts for much of the differences in total per capita costs for medical care between these two communities.

These statistics of variation carry broad implications. For many common conditions, the academic standards for medical practice as now constituted are not based on well tested medical theory. Physicians, patients, those who pay for care and those in policy positions remain ignorant of the health care outcome consequences of spending vastly different proportions of the gross national product (GNP) on health care. The Boston-New Haven comparison shows that the scientific basis of medicine as now constituted does not understand the significance of an investment of upwards of 16 percent of GNP (as for Bostonians) from 9 percent (as for New Havenites). The National Center's Outcome Assessment Program establishes a systematic approach to obtaining answers to such questions about the diminishing returns of medical care.

The Standards for Truth and Strategies for Evaluation

Although the magnitude of the variations in utilization and costs illustrated by the New Haven-Boston comparison indicates an efficacy problem of enormous proportions, I believe the problem is manageable. The experience gained from drug evaluations teaches a good deal about how to approach the assessment of medical efficacy. Drugs undergo an orderly process of evaluation and much of this strategy--but not the regulatory process--is being adapted by The National Center. Phase I studies establish safety; phase II studies develop evidence, obtained through non-experimental studies, that the treatment is effective. Many drugs do not survive these studies. The uses of hospitals, surgery and invasive diagnostic tests have not, as a rule, received this kind of careful study and it is very likely that many theories used in everyday practice will not withstand critical examination.

The initial phase I and II assessments that The National Center plans under S.2182 can be accomplished with surprising speed and efficiency. A published literature exists which can be critically appraised to identify the key controversies needing assessment, establish initial estimates for outcome probabilities and identify gaps in information that need to be filled. Most of the treatments needing assessment are paid for by medical insurance. For these, a good deal of unsynthesized but vitally important data for outcome research exists in the nation's insurance claims data systems. Moreover, the claims data provide a means for locating patient records and the patients themselves, so missing information--clinical data, laboratory findings and functional status of patients--can be efficiently obtained. The data assembled on safety and efficacy through these non-experimental studies can then be integrated to test clinical theories.

An Example of a Phase I and II Assessment: Prostatectomy versus Watchful Waiting for "BPH"

Let me give a concrete example of a phase I and II assessment that has already been accomplished, thanks to funding by The National Center and The John A. Hartford Foundation. The assessment was published in May of this year as a four part series in the Journal of the American Medical Association.[1] At issue is the treatment of prostatism or obstruction of the urinary tract due to benign hypertrophy of the prostate gland or "BPH". BPH is a very common condition, affecting the majority of men by the time they reach the seventh or eighth decade of life.

One common treatment for BPH is an operation, a prostatectomy. The use of prostatectomy shows striking variations among neighboring communities so that in some places about ten percent of men undergo this operation by age 85 while in other communities the proportion can be as high as fifty percent. The treatment is the most expensive major operation paid for Medicare: program outlays for hospitalization costs and surgery fees in 1985 were well over a billion dollars.

Another common treatment for BPH is watchful waiting. In communities with low rates of prostatectomy, proportionately more men with BPH are treated by this alternative strategy that emphasizes the viewpoint that prostatectomy is an elective procedure, reserved for those with truly bothersome symptoms.

Four years ago, our research group and physicians participating in Maine's Medical Assessment Program formed an assessment team to consider the causes of variations in rates of prostatectomy among Maine communities. These discussions (and a review of the scientific papers published on BPH) uncovered an important and unsettled controversy concerning the indications for the operation:

> Many physicians hold to the theory that prostatectomy should be performed early in the course of BPH as a preventive measure. They reason that if the operation is delayed, the patient will be older and be at higher risk when the operation finally becomes unavoidable; if the operation is delayed, life expectancy is reduced. For most patients, according to this theory, watchful waiting is not a reasonable option.
>
> Other physicians argue that the need for the operation is not inevitable, that for most patients it does not improve life expectancy and that the primary reason for an operation for such patients is the relief of symptoms and improvement in the quality of life. According to this theory, watchful waiting is a reasonable option for patients who prefer to live with their symptoms in order to avoid the risk of the operation.

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[1] The Journal of the American Medical Association, Volume 259, number 20, May 27, 1988

The assessment team tested this conflict in theory to reach several conclusions. Using evidence from the literature and from claims data, the assessment demonstrated that the preventive theory was wrong: an operation in patients with uncomplicated BPH--and most patients are like this--very likely causes a slight decrease in life expectancy. The assessment thus confirmed the opinion of those physicians who felt the operation was justified on the basis of its value for reducing symptoms and improving the quality of life. Interview studies with patients before and at three, six and twelve months after surgery showed that the value of the operation for most patients rests in its superior effect over watchful waiting in reducing symptoms and improving the quality of life. But these gains are available only to patients willing to take the risks of the operation which include death, failure to improve symptoms, impotence and incontinence. The decision to undergo the operation is thus highly dependent on patient's preferences for outcomes and attitudes toward risk.

By clarifying controversies, establishing correct theory and providing detailed probability estimates for the full spectrum of relevant outcomes, some of which had not been previously studied, the assessment has immediate practical value for improving clinical decision making. The practice style related causes of variation in prostatectomy rates were traced to an incorrect belief in the preventive theory of early prostatectomy and failure to take patient preferences into account in recommending prostatectomy. The remedy for unwanted, practice style variations requires the active engagement of the patient in the decision. It involves informing physicians and patients of the risks and benefits of prostatectomy and its alternative, watchful waiting.

Principles to Guide the Mandate to Extend Systematic Assessments

The nature of the assessment problems and the way innovation occurs in most fields of medicine suggest certain principles to guide the mandate to extend the systematic assessment of outcomes to include surgery, diagnostic tests and the uses made of hospitals:

1. Assessments must be conducted according to the principles of "regular science" as part of the nation's system of peer reviewed medical research.

2. Assessments must be ongoing: the nature of innovation in medicine requires continuous evaluation and reevaluation as new theories arise.

3. Priorities must be set: The assessments done first must be those that matter most.

4. Regulation won't Work: innovation for most medical treatments is decentralized and assessments not easily mandated through formal regulation.

5. Rapid completion is essential: Assessments must produce useful results within reasonable time.

These principles are reflected in the design and philosophy of The National Center's Outcome Assessment Program:

1. Regular Science. The uncertainties we are talking about are fundamentally scientific uncertainties that can only be resolved by obtaining information and using it to test theory. The needed improvements in the scientific basis of clinical decision making depend on these assessments and they must proceed in an orderly fashion to develop a body of knowledge based on proven rules of evidence and formally structured peer review. The intellectual rigor now commonplace in the biomedical sciences must be the standard. In the final analysis, the authority and effectiveness of the assessments depend solely on their credibility as objective science. The principle of scientific independence is the protection that assures a balanced, unbiased source of information about what is known and what remains controversial in the evolution of clinical theory. The National Center, as part of the federal government's scientific establishment, offers these assurances.

2. Continuity and Continuing Responsibility. Innovation in medicine is dynamic and the need for assessments is an iterative, ongoing one. Information needs continuous updating and improvement; new assessments will be needed as new theories develop and old ones evolve. The BPH assessment team uncovered several new treatment theories which need assessment. We found a new approach to BPH based on the use of microwaves to shrink the prostate; a new, less invasive, operative approach based on a simple incision of the gland, and a new idea that BPH can be treated with a balloon that is expanded to push the prostate tissue aside. We also learned about drugs which may work. These theories need testing. The National Center's Outcome Assessment Program establishes assessment teams with ongoing responsibility to keep abreast of new developments and to perform (or influence others to perform) adequate phase I and II studies. Their recommendation on the need for randomized clinical trials offers further guidance to the rational evaluation of medical theory. Like their counterparts in biomedical medicine, the scientists involved need to make career investments in a problem

area. The experience and knowledge are accumulative. Assessment projects dealing with major human illness such as BPH need to be continued indefinitely.[2]

3. Priorities are Needed. The assessment projects that are established first should be those that matter most to patients and to those who are concerned with the quality of care and the allocation of scarce resources. Most would agree that the focus needs to be on testing the alternative ways of dealing with common medical problems for which at least one treatment option is known to be costly and/or risky. I have listed my nominations in an accompanying table. Even though my list of priority illnesses or conditions is small, it covers the large majority of costly variations in surgery and hospitalization such as those illustrated by the New Haven-Boston comparisons. Assessments in these areas would affect most patients who are now, according to some theories, candidates for surgery or hospitalization.

4. Regulation Won't Work. The mandate to extend evaluations to the use of surgery, diagnostic tests, and hospitals cannot be accomplished through regulation. There is an essential difference between the research and development strategies of the drug industry and the dynamics of innovation for most medical practices. Drugs follow a linear process of technology development and assessment, from the bench to the animal laboratory and finally to human experimentation. The mandate to evaluate is easily accomplished through regulation tied to the license to market and the resources needed for evaluation are provided as part of corporate policy. But most medical innovations develop as part of the problem solving activity of physicians in their daily encounters with patients, in decentralized environments where there are few resources available for evaluation. Assessment teams are an alternative to regulation in a situation where regulation is not likely to succeed. They accomplish their mandate for evaluation because team members are drawn to the intellectual, scientific and ethical questions of efficacy, because their professional careers are vested in the evaluative sciences and because The National Center provides the resources needed to make the evaluations happen.

5. Rapid Completion is essential. The principle, "quick is beautiful" I borrow from Freeman Dyson who notes that projects that are timely and offer results in a few years succeed while those with longer time frames tend to fail. The assessments The National Center will undertake fit this principle well. The utility of phase I and II studies does not depend on the subsequent randomized clinical trials they may generate. As the prostatectomy assessment illustrates, substantial clarification of clinical theory is possible on the basis

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[2] The BPH assessment project uncovered a surprising finding that serves to emphasize why ongoing assessments are needed. An operation on the prostate can be accomplished as an "open" prostatectomy requiring an incision through the skin and the complete removal of the obstructing prostate tissue or as a transurethral resection of the prostate, or "TURP", using a resectoscope introduced through the urethra. The TURP has replaced the open prostatectomy as the treatment favored by most physicians in the United States and Europe, (but not in Israel). This shift in practice pattern from one operation to the other occurred without adequate assessment. Using insurance claims data from the mid 1970's when open prostatectomies were still performed in this country and Canada, our assessment team discovered that the incidence of operative failure (measured by the need for a second prostatectomy or subsequent diagnostic examinations and the incidence of strictures) is substantially higher following TURP. We are currently pursuing the opportunity for further study in Israel where open operations are still performed. Had The National Center's Outcome Assessment Program existed ten years ago, we would not now be faced with the uncomfortable possibility that the more effective treatment has been replaced.

of these studies alone. The Congress, by investing in The National Center's Outcome Assessment Program, can expect substantial results within two to three years.

The Response of the Profession

The Congress can also expect cooperation from the medical profession as it implements policy to do away with the double standard for truth in medicine. The assessments of health care outcomes conducted under S.2182 will challenge the theories and practice patterns of the nation's physicians, but the challenge will be on the high ground of scientific evidence and an imperative all physicians recognize--the need to do what is best for patients. All physicians share the burden of uncertainty. They have been forced to act on behalf of their patients, using the theory and information they have and with little help from the evaluative sciences. More than anyone, they want to know what is best for patients. The actions of physicians working in Maine's Medical Assessment Program exemplify the constructive response practicing physicians make to the challenge to assess medical practice. The leadership among the American Medical Association, the Societies representing the nation's medical specialties and the Joint Commission on the Accreditation of Healthcare Organizations understand this need and they are moving to promote professional responsibility for assessment of practice patterns. The nation's academic medical centers are increasingly aware of the need to support the growth of the evaluative clinical sciences and outcomes research. We can foresee the active participation of practicing physicians as well as academic medicine in The National Center's Outcome Assessment Program to improve the scientific basis of clinical decision making.

Suggested Priority Conditions or Illnesses for Phase I and II Assessments Under the National Center for Health Services Research and Health Care Technology Assessment's Patient Outcome Research Program (S.2182)

Condition	Treatment Controversies
Stable Angina	Bypass Surgery vs Angioplasty vs Drugs
Unstable Angina	Bypass Surgery vs Angioplasty vs Drugs
Arteriosclerosis Causing Stroke	Endarterectomy vs Drugs;
Peripheral Vascular Disease	Bypass Surgery vs Angioplasty vs Medical Management

Lens Extraction	(by type of surgery) vs Watchful Waiting
Gallstones	Surgery vs Stone Crushing vs Medical Management vs Watchful Waiting
Arthritis of the Hip and Knee	Surgery (by type) vs Medical Management
Non-Cancerous Conditions of the Uterus	Surgery (by type) vs Hormone Treatment vs Watchful Waiting
Prostatism	Surgery (by type) vs angioplasty vs drugs vs watchful waiting
Ear, Nose & Throat Conditions	Surgery by type vs various drugs
Herniated Disc	Surgery vs various medical treatments
Acute and Chronic Medical Conditions:	
Back Pain/Strain Gastroenteritis	Hospitalization vs ambulatory-based care; ICU vs Usual Ward Care
Respiratory Disease Heart Disease	

QUESTIONS OF SENATOR JOHN HEINZ FOR THE RECORD
Dr. John Wennberg, Dartmouth

QUESTION: Your research in Maine suggests that physician practice patterns can be changed with the right type of educational and peer interventions on a voluntary basis. Yet, a recent UCLA study examined the effect of NIH's 11 year old Consensus Development Program on the behavior of participating physicians and found that practice approaches did not change to reflect state of the art science and practice standards.

To your knowledge, have there been studies on the relative success of different approaches to changing physician practice patterns? What have we learned so far? Do you believe that research on patient outcomes will have any long-reaching effect on physician behavior if we rely solely on voluntary approaches to change?

QUESTION: Of the 13 conditions and illnesses you suggest as priorities for patient outcome research, are we far enough along in our research in any of these or in other high volume/high cost procedures (e.g. cataract surgery or coronary bypass surgery) to proceed to develop practice standards that can be used to guide physician practice and consumer choice? How quickly can research on new priorities produce findings?

Dartmouth Medical School
DEPARTMENT OF COMMUNITY AND FAMILY MEDICINE
Hanover, New Hampshire 03756

October 17, 1988

Senator John Heinz
United States Senate
Senate Dirksen
Washington, D.C. 20510

Dear Senator Heinz:

I want to apologize for the long delay in answering the note I received from your office in July which contained two questions for me in followup to the Subcommittee's Hearings on Health Outcomes Research. I understand from Edgar Danielson that the record is still open, so I hasten to comply.

You ask about the relative success of different approaches to changing physician practice patterns. Have studies been made? What have we learned so far? Do I believe that research on patient outcomes will have any long-reaching effect on physician behavior if we rely solely on voluntary approaches to change?

John Eisenberg, in a recent book on physician practice patterns, reviewed the evidence on the effect of various strategies for changing physician behavior. The picture he paints is definitely a mixed one. Outcome studies that clearly demonstrate the error in a particular treatment theory usually have a profound impact on practice patterns. The randomized clinical trials of gastric freezing (an idea about how to treat ulcers) showed that the device was worthless and this led to quick changes in practice patterns. A similar change in practice patterns was recorded after the Wineberg procedure--a now extinct operation on the heart to treat angina--was found to be no better than a placebo operation.

The problem gets much more difficult when a treatment seems to work for some but not for all patients. This situation seems the rule rather than the exception. As is the case for most chronic illnesses, the severity of a particular patient illness rests on a spectrum. When does a patient benefit? When are the benefits worth the costs? Even though these might be known in the abstract--ie, from some randomized clinical trial--translating this information into practical decisions can be very difficult.

What we see in the real world for these kinds of decisions is that the supply of resources tend to set the threshold.

This is most clearly demonstrated for medical admissions where the supply of hospital beds is correlated closely with the admission rates and hence with the costs of care. In my view, policy makers interested in cost containment have not focused enough attention on this fact. Remember, it is the medical admissions--foremost, admissions for back pain, gastroenteritis, and chronic pulmonary diseases--that are responsible for the gross differences in per capita expenditures between Boston and

New Haven which, as I say in my testimony, amounted to the equivalent of more than 16 percent of GNP in 1982 for Bostonians compared to 9 percent for New Haven residents. If outcome assessments demonstrated conclusively that the health of patients is not improved by this extra expenditure, then there would be good grounds for policies to restrict the numbers of beds per capita to numbers closer to the New Haven rate.

For treatments that are elective in nature--and this involves most of the surgical treatments on my list of 13 conditions--there is another approach to changing behavior which involves the patient as well as the physician. Let me illustrate what I mean by an example, the treatment of men with a prostate condition. We recently completed an extensive assessment of alternative treatments of this condition, following the outcome assessment procedures I have recommended for the National Center. The results showed that a prostatectomy, performed early in the course of prostatism, does not extend life, rather it results in a slight decrease in life expectancy. The operation thus makes sense only for reducing symptoms and improving the quality of life. The surgery has some risks, including operative mortality, impotence and incontinence. Those who choose not to have the operation cannot expect dramatic improvement in their symptoms (although some do get better, many stay the same and some get worse), but they do avoid the risks of surgery.

Our study made one thing very clear: patients with the same objective severity of symptoms and objective physical findings and diagnostic tests held very different attitudes concerning how much they were bothered by their symptoms. The only way to ascertain whether an operation or watchful waiting is the appropriate treatment for a specific patient with prostatism is to ask him whether his symptoms bother him enough so that he wants to take the risk of surgery to obtain the possibility for the benefit.

The conclusion of the assessment is that the standard of care for this operation must be based on informed patient decision making. As part of the assessment, we evaluated the entire scientific literature, claims data, and patient interview studies to obtain detailed estimates of the chances for each of the outcomes that matter to patients; death, morbidity, complications, symptom relief, and improvement in quality of life. We thus found ourselves in a position to inform patients about their options. But how is this to be done?

A new technology--computer assisted, interactive video disc--is the answer. This technology allows the storage of a very large amount of information and it can be retrieved in a way that permits information to be presented to a patient that is specific to his particular symptom state and the severity of his underlying illnesses. Moreover, film vignettes of patients who have had good as well as adverse outcomes can be shown so the patient has a way of knowing what his possible medical futures might be, dependent on what he chooses. The idea of our "Shared Patient Decision Making Procedure" is that it would be shown in physicians offices. We emphasize the word "shared" to indicate the departure from patient dependency on the physician as the interpreter of what is best. In our opinion, it offers a real opportunity to shift the burden of decision making and thus open up medical decision making to take patient preferences much more directly into account than is now the case. The assessments make information on outcomes available in a systematic way, and video disc technology provides a way for reducing and presenting information in a way that is meaningful for patients. I have enclosed a copy of a recent Fortune Magazine article describing this strategy and would be glad to demonstrate it to you and your staff.

You ask a second question: Of the 13 conditions and illnesses I suggested as priorities for patient outcome research, are we far enough along to develop standards of practice to guide physician practice and consumer choice? How quickly can research on new priorities produce findings?

The prostatectomy assessment described above is an example of the research I am recommending. I think you will be pleased to know how little time it takes to achieve significant clarification of practice theory. Many of the physicians we interviewed in Maine and many of those who have contributed to medical textbooks and journals advised patients to have the operation on the belief that early operation--when symptoms are mild or moderate--saves lives because men get operated upon early when they are healthier. For a number of reasons, this theory turned out to be incorrect. Thus, we are able to conclude that except for a small group of patients with chronic obstruction, the standard of practice must be informed patient decision making, where patients weigh the risks of surgery against its benefits, compared to how badly they are bothered by their symptoms. We were also able to develop the interactive video disc and are now beginning formal clinical studies to evaluate its impact on patient and physician behavior.

These studies--from their initial conceptualization to the publishing of our findings last May in the Journal of the American Medical Association--were completed over a four year period. Now that the methods have been developed, they can be applied to the remaining 13 conditions in a much more efficient manner. With full funding and with a well administered program that mobilizes the talent I know is available in this country, results that are useful for patient and physician decision making can be ready within two years. We are not talking in terms of decades; our time frame is in the short term.

But I want to end with a final point, one I made in my testimony. The need for the evaluations I am talking about is an ongoing one. Problem solving in medicine is a dynamic, exhilarating process that continually leads to new ideas and innovations. New theories on how to handle human illnesses constantly emerge. They need to be identified and evaluated. The assessment teams I have in mind need to be established with the long-range objective of providing physicians, patients, and the public with the critical intelligence we need in order to separate good theories from bad ones. In the course of our prostatectomy assessment we discovered many new ideas about how to treat prostatism, including drugs, balloon angioplasty, a simple incision in the base of the prostate gland, and a novel use of microwave technology to correct the problem. Each of these ideas and those that will succeed them in the future needs the careful attention of an assessment team.

Sincerely,

John E. Wennberg

John E. Wennberg, M.D.
Professor of Epidemiology

JEW:amb
Enclosure

LOOKING AHEAD

MEDICAL CARE'S NEXT REVOLUTION

Believe it or not, doctors often don't know which treatments pay off best for patients. A vanguard of physicians hope to conquer this ignorance.

■ *by Edmund Faltermayer*

CONSIDER what doctors, to say nothing of patients, don't know about the value of just one procedure. Each year about 80,000 Americans get a carotid endarterectomy, a kind of Roto-Rooter job on clogged neck arteries. Typically costing $9,000, counting the bill for a hospital stay, the operation is designed to prevent strokes. Another triumph of modern medicine? Or an overly risky, overdone alternative to cheaper drug therapy? Incredibly, no one knows for sure, and no one is tracking the patients on a systematic basis to find out.

The same holds true for scores of other medical ministrations. Food companies know the impact of a redesigned ketchup bottle on sales. But the virtuosos performing hysterectomies, installing pacemakers, and bypassing diseased coronary arteries have only patchy information about the real payoffs. "Half of what the medical profession does is of unverified effectiveness," asserts Dr. Paul M. Ellwood Jr. of Minneapolis, in a phalanx of physicians who want to cut down on the guesswork.

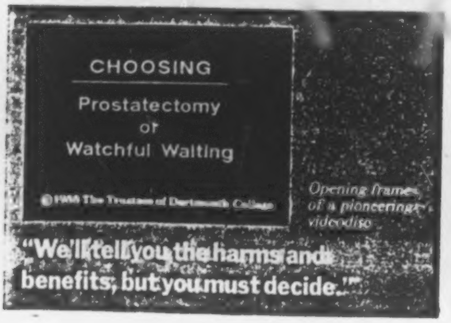
Half of something as stupendous as the U.S. health bill—now 11.4% of GNP, or nearly twice what the military gets—implies a huge ore body that could be mined for savings. That should be of special interest to business, which picks up the biggest chunk of medical expenditures. Health insurance premiums have jumped anew in 1988, following several years in which companies successfully slowed the rise.

Abetting the persistent upward trend is what one consultant calls "MD-ification." Corporations, for all their new cost-containment mechanisms, don't know enough to go eyeball to eyeball when professionals are determined to do an operation. Yet business executives would be shocked if they knew of the doctors' own uncertainties. The problem is rare in the cut-and-dried matter of treating acute afflictions—prescribing penicillin for pneumonia or setting a broken bone. But doctors increasingly toil in the murky area of chronic ailments: arthritis, angina chest pain, impaired vision. Here the question of which treatment is best can be settled only with data.

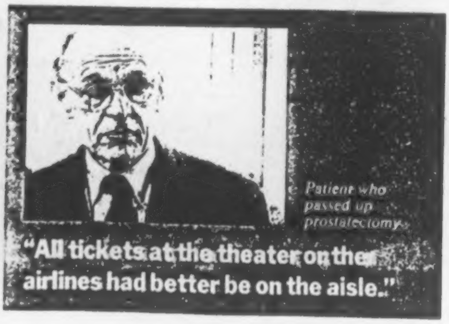
The need for much more of it has never been so urgent. The new law liberalizing Medicare payments for catastrophic illness promises to boost demand for health services still further. So could the extension of health insurance to the uninsured (FORTUNE, September 26). A rollback of ignorance would bring huge benefits. With better data, business could effectively challenge proposed treatments. Many doctors might enjoy better protection against malpractice suits. Patients could be the biggest gainers. If the pros and cons of alternative treatments were better known and conveyed in lay language—a rarity now—patients could have a real say in how they are scanned and sliced.

THE GROWTH of health maintenance organizations, whose membership has tripled to 31 million in the past six years, was supposed to supply much of the missing knowledge. Operating on a fixed "subscription" payment set annually for their members, HMOs have strong reasons to study their centralized patient files for ways to weed out wasteful procedures. Alas, such studies have not been extensive. Until recently, HMOs have managed to save plenty of money just by cutting down on hospital stays.

REPORTER ASSOCIATE *Reed Abelson*


CHOOSING
Prostatectomy
or
Watchful Waiting
©1988 The Trustees of Dartmouth College
"We'll tell you the harms and benefits, but you must decide."

Opening frames of a pioneering videodisc


"All tickets at the theater or the airlines had better be on the aisle."

Patient who passed up prostatectomy

TOO MUCH DOCTORING, SAY THE DOCTORS

PROCEDURE	"UNJUSTIFIED"	"DEBATABLE"
Coronary artery bypass (cost: $37,000)	14%	30%
Carotid endarterectomy ($9,000) Removal of deposits from clogged neck arteries	32%	32%
Pacemaker implants ($9,000)	20%	36%
Coronary angiography ($3,400) X-rays of heart arteries injected with dye	17%	9%
Upper gastrointestinal tract endoscopy ($750) Visual examination with fiber-optic device	17%	11%

[illegible]

Big savings might result from better data on which patients really need fancy operations and tests. Panels of doctors developed the criteria upon which these findings are based.

That's particularly disappointing to Ellwood, 62, a witty, searingly insightful visionary who heads a medical think tank called InterStudy. He led the proselytizers when the concept of prepaid care was barely known in the early 1970s, and the very term HMO is his. But the rates at which HMO doctors perform various procedures, it turns out, are not so different than elsewhere. Caesareans and other debatable operations, moreover, are way up, just as they are in the country at large. "What HMOs haven't done, which I had hoped, is manage the *content* of medical care," Ellwood says. Why not? "HMO doctors are ignorant, just like all doctors."

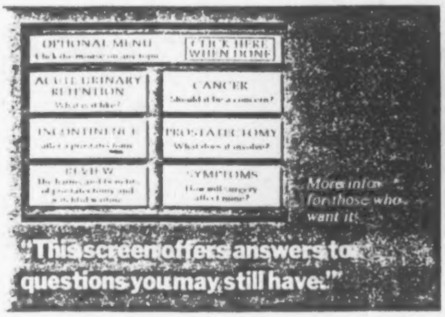
Having shaken up the medical system once, Ellwood seeks to do it again. He wants the records of millions of encounters between doctor and patient, whether in HMOs or in the traditional fee-for-service system, recorded in computers and the results of treatment routinely monitored through follow-up questionnaires to patients. "When we're spending a half trillion dollars a year on health care," Ellwood says, "we ought to know what works." Dr. Arnold S. Relman, editor of the influential *New England Journal of Medicine*, says that "assessments" and the general concern about quality are "the third revolution in medical care," the first being the spread of health insurance and the second the revolt of the payers. Physicians must be in charge of the third revolution, Relman says, for only they have the training.

Though better information could put an end to some fat fees, doctors are starting to rally behind the idea. Many fear a loathsome alternative: another round of heavy-handed cost controls imposed by nondoctors. Dr. William L. Roper, a pediatrician who runs the federal government's Medicare and Medicaid programs, adds that "those on the firing line want better information so they can do a better job for their patients."

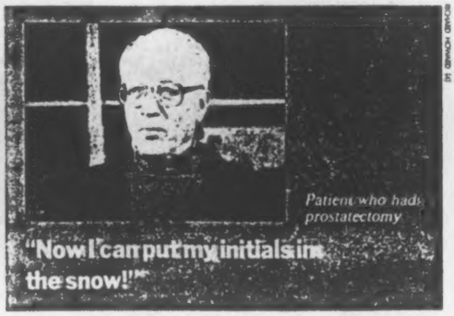
MEDICAL RESEARCH is hardly in short supply. Teams of doctors report all the time on the success of this new operation or that diagnostic device. But the studies often leave important questions unanswered because the number of patients is small, the scope of inquiry narrow, or the methodology faulty.

Take the controversy on how to treat hardening of the leg arteries, which can turn walking to agony and lead to amputation. Doctors have four main alternatives: Do nothing, prescribe physical therapy and exercise, perform bypass surgery, or use a newer procedure called percutaneous transluminal angioplasty, or PTA—inserting a balloon and inflating it to clear the arteries. During a 1987 visit to Duke University's Center for Health Policy Research and Education, Dr. Raphael Adar, a prominent Israeli surgeon, pored over 39 papers on the use of PTA for the leg. As disclosed in a recent issue of *Health Affairs* magazine, Adar found all the studies deficient. Not even the better ones reported on the outcomes of greatest concern to patients: the relief of pain and the continued ability to walk.

"For people who read this kind of information, it's very frustrating," says Dr. David Eddy, a professor of health policy at Duke and a critic of much medical research. Meaningful numbers on the cost effectiveness of tests can also be hard to come by. When left in the dark, Eddy says, panels of doctors charged with evaluating the tests' usefulness fall back on their own best



"This screen offers answers to questions you may still have."



"Now I can put my initials in the snow!"

clinical impressions. One panel was asked to estimate the effect of a particular testing regimen—annual sigmoidoscopy and stool specimens—in reducing cancers of the colon and rectum, which annually take the lives of about 60,000 Americans. The answers ranged all the way from a 5% reduction in deaths to 95%.

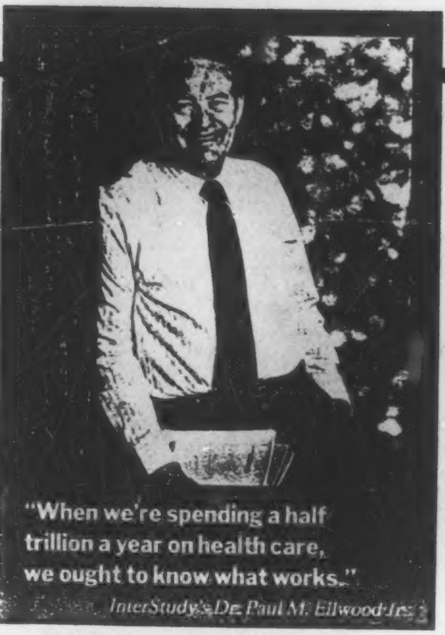
Elsewhere, shafts of knowledge have begun to pierce the darkness. Financed primarily by foundation funds, Rand Corp., a research organization in Santa Monica, California, has looked into those carotid endarterectomies. First the researchers studied the literature and listed the hundreds of situations in which the treatment might help. Then they asked a panel of nine doctors to rate its appropriateness in each situation and reviewed the records of 1,302 Medicare patients in three areas who got the operation in 1981.

The conclusion, published earlier this year: Just over a third of the carotid endarterectomies were appropriate, while 32% were borderline. The other 32% should not have been performed, mainly because the symptoms did not seem serious enough to warrant the considerable risks. During the hospital stay, 3.4% of all the patients who got carotid endarterectomies died because of complications from the operation. Another 6.4% had strokes—just what they had hoped to avoid. The researchers recommended that the operation be curtailed.

Three other procedures have come under Rand's scrutiny. As the table on page 27 shows, the researchers found two diagnostic tests much in vogue to be overdone, though not as greatly as some critics assert. But Rand recently came down hard on coronary artery bypass surgery.

More than 230,000 Americans had coronary bypass operations last year, twice as many as in 1980. Few are life-and-death affairs performed on patients who have just had heart attacks. The aim generally is to relieve chest pain. Two alternatives—drugs and clearing the coronary arteries with an inserted balloon—are less costly and sometimes just as effective. Reviewing 386 bypass operations done in three hospitals in 1979, 1980, and 1982, Rand concluded that only 56% were clearly appropriate.

"Appropriateness" studies are a giant step forward, but they have limitations. They are based on what committees of specialists believe is the right time to test or operate. To *know* what works requires surveys of how patients made out later on—typically at least a year later. Contact with patients often ends when they walk out of the hospital or the doctor's office. Dr. John E. Wennberg, an epidemiologist at Dartmouth Medical School, made some fascinating discoveries in a follow-up study of men who underwent prostate operations.



"When we're spending a half trillion a year on health care, we ought to know what works."

InterStudy's Dr. Paul M. Ellwood Jr.

WENNBERG, 54, has a quietly earnest manner that befits one with a sense of mission. Because doctors don't know the probable outcomes of one treatment vs. another, he says, medicine is in an "intellectual crisis." When studying health care patterns in rural New England in the 1970s, Wennberg was struck by significant variations in the rate at which doctors performed tonsillectomies, hysterectomies, and other operations. Later he found sharp differences in medical spending in Boston and New Haven, Connecticut. Though the health characteristics of both cities' populations are similar, Boston was spending the equivalent of 16% of GNP on medical care to New Haven's 9%.

Prostate operations, which varied from place to place by a factor of four in the earlier New England study, provided an opportunity for Wennberg and his colleagues to pioneer. Few are performed to save a man's life; even cancer of the prostate is rarely fatal. But many physicians have long advised preventive surgery to avoid a greater risk when the man is older. More than 300,000 operations on benignly enlarged prostates were performed in the U.S. last year at a cost of about $3,500 each.

Two-thirds of Maine's practicing urologists agreed to participate in Wennberg's survey of patients getting prostatectomy operations, starting in mid-1983. Most of the patients were 65 and older. An initial interview detailing each man's symptoms was followed by another three months after surgery and telephone interviews after six and 12 months. The findings, based on 263 men who completed all three postoperative interviews, were published last spring in the *Journal of the American Medical Association*. The researchers found that the "preventive" argument for surgery is wrong, for the operation caused a slight decrease in life expectancy. It is justified solely, they concluded, for what physicians call quality-of-life reasons: The patient is having problems urinating.

For most of the men, the quality of life improved over a year: 78% reported mild or no symptoms and 16% moderate problems, leaving only 6% with serious symptoms. The results of the survey have been incorporated into a videodisc that will be tested before focus groups of doctors and patients this fall. Running 28 minutes, not counting additional information the viewer can select at the press of a button, the disc is a breakthrough in medical consumer information.

To background music, the title comes on screen: *CHOOSING—Prostatectomy or Watchful Waiting*. Dr. Charles Culver, a psychiatrist who serves as narrator, says the operation brings "improvement at a price.

continued

"The fundamental assessments of whether procedure A or B works better just haven't been done."

Dartmouth's Dr. John E. Wennberg

We'll tell you the harms and benefits, but then you must decide." Four patients appear. One of two who agreed to the operation can scarcely contain his enthusiasm: "Now I can put my initials in the snow!" One who chose "watchful waiting" is asked whether his condition interferes with daily activities. His mildly jovial reply: "All tickets at the theater or the airlines had better be on the aisle."

While pointing out the advantages of the operation, the narrator cautions that the negatives must not be overlooked. Within three months of the operation, 8% of the men were back in the hospital with serious complications. Others encountered new difficulties: 4% of those who never had the problem became incontinent to some degree, and 5% of those who previously had erections became impotent. If the videodisc were generally available, many men would probably turn down the operation, articularly those who don't have severe roblems.

Not too many years hence, Wennberg opes, a typical doctor's office will have erhaps a score of videodiscs covering as nany illnesses. To those accustomed to the lictatorial style of medicine, it might seem itopian to expect doctors to furnish information enabling patients to argue with hem. But many doctors, particularly family hysicians, might welcome the chance to elp patients make up their minds. It's a afe bet, too, that payers would encourage he practice.

Wennberg favors a big increase in unding for a little-known federal agency alled the National Center for Health Serices Research and Health Care Technolgy Assessment. Despite the impressive ame, its budget has declined since the 970s, to $47 million. Wennberg and oths want the figure boosted to at least 00 million. That would finance more udies like the one on prostatectomies. ys Wennberg, who notes that the drug dustry spends billions evaluating its oducts: "The fundamental assessments whether procedure A or B works better st haven't been done."

Ellwood has something far more ambitious in mind, which he calls "outcomes management." The health system would keep track of *all* patients and their progress after treatment. Initially the goal would be to track chronic illnesses whose treatment is of uncertain value. Doctors would constantly adjust their procedures in response to feedback on what works best, much as a retail chain adjusts its buying according to on-line data that show what is selling.

THE BEGINNINGS of such a system can already be discerned. Medicare boss Roper's outfit, the Health Care Financing Administration, has agreed to pay for pilot studies of outcomes management at ten Midwestern HMOs. Quality Quest, a subsidiary of Ellwood's InterStudy, will be in charge. One of the first tasks is to select a short, standardized "quality of life" questionnaire in which patients would describe their condition before treatment and later on. Such questionnaires, developed in the past few years by Boston psychometrician John E. Ware and others, include general queries on the patient's well-being and ability to function as well as some related to his specific illness. Sample question for a victim of heart disease: "Do you need to sleep sitting up at night?"

Ten other organizations are interested in financing pilot studies, among them the state of Massachusetts and the Blue Cross and Blue Shield Association in Chicago. When asked what he thinks of Ellwood's idea, the association's president, Bernard R. Tresnowski, responds, "Right on!"

"The health care system," Ellwood declares, "has become an organism desperately in need of a central nervous system that can help it cope with the complexities of modern medicine." Until a single national databank can be created, he would settle for a sharing of information among insurers and health organizations.

One of the biggest data pools is Health Information Reporting Co., set up three years ago by nine of the largest Blue Cross and Blue Shield plans and the national association to analyze payment and utilization trends among 15 million members. Another is the federal government, which has years of claims data covering 32 million Medicare recipients. In neither case are patients surveyed later on to gauge the effectiveness of treatments, though the Blues and Medicare are both interested in the idea. Data on patients' fates are already gathered, however, for some major illnesses. For example, the National Cancer Institute has access to data on more than a million patients, and a pool of data banks called Aramis tracks 28,000 arthritis victims. Some of the findings are available to the public.

Doctors' offices, which long ago turned to computers for billing, are still paper holdouts when it comes to maintaining patients' medical records. Many hospitals and health care organizations, on the other hand, have gone heavily electronic. Intermountain Health Care of Salt Lake City, which in 1975 took over hospitals formerly owned by the Mormon church, has created what may be the best computerized clinical database in the U.S. At some bedsides, doctors can call up a patient's history on terminals, including past test results and even recommended procedures. Dr. Brent James, who is director of medical research at Intermountain, plans to add follow-up surveys of discharged patients.

Computers already influence what doctors do. At Wishard Memorial Hospital in Indiana University's Indianapolis medical center, at least 400 doctors have access to computerized patient records. In an experiment at reducing blood tests in the mid-1980s, terminals began flashing information on the odds that each of eight common tests would reveal a suspected abnormality. Result: Billing for the eight tests dropped 9%.

United HealthCare, a Minneapolis firm that owns seven HMOs and provides contractual services to 16 others, maintains prescription records for two million people. About 500,000 live in the Twin Cities area, where pharmacies are tied into a computer network. When the computers spotted excessive use of diet pills a few years ago, the HMOs stopped paying for them and doctors cut down on prescribing them.

The next medical revolution will quickly sputter if it merely amasses information that doctors ignore. It's unlikely insurers will let that happen. Willis Goldbeck, president of the Washington Business Group on Health, a national organization of large companies with employee medical plans, says that "physicians will change their behavior if the new knowledge is tied to reimbursement."

SUCH TIES are already being forged. Citing Rand Corp.'s studies, California Blue Shield has decided to require a second opinion on carotid endarterectomies. One of Rand's senior researchers on the medical studies, Dr. Mark Chassin, has become senior vice president of a new company called Value Health Sciences, which is turning the Rand findings into a computer software program that insurers will be able to use as a cheaper alternative to a second doctor's opinion.

Thus the payers are using doctor-generated information to control what doctors receive. The implications cause a few shivers among physicians. Will medicine become a "cookbook" affair, with the treatment for each set of symptoms limited to what shows up on a computer screen? No two patients are alike, after all, and doctoring has always been a subtle blend of feel and fact. Roper, for one, doubts that cold science will eliminate the need for healing art. Airline pilots are required to follow all sorts of standard checkout procedures, he says, but flying the big ship still calls for experience. By putting as much uncertainty as possible behind them, doctors should find their calling more satisfying than ever. ■

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NCHSR program note

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH
AND HEALTH CARE TECHNOLOGY ASSESSMENT
18-12 Parklawn Bldg. • Rockville, MD 20857 • 301/443-4100

September 1986

NCHSR Solicits Proposals for Research in Medical Practice Variations and Patient Outcomes

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) encourages researchers to submit grant proposals for studies of variations in the patterns of medical practice and their effects on patient outcomes and the costs of care.

The program is designed to provide research information to address important clinical questions as well as immediate health policy concerns.

Proposals should focus on medical conditions which have particular relevance to the Medicare program. Treatments and procedures to be studied should be those which are significant in terms of Medicare beneficiaries' use of health services, length of hospitalization, costs and risks, and for which data indicate highly varying patterns of use.

Research in health services, in this country and elsewhere, indicates that neither the patient's presenting complaint nor the diagnostic label assigned is the main determinant of how health care resources are used. Variations in utilization reflect a complex interaction of clinical, social, environmental, economic and psychological factors which affect the relationship between patient and provider. Variations are appropriate if they arise from differences in the needs and concerns of individual patients, and if the alternative patterns of care are known to be equivalent in effectiveness and efficiency.

However, physicians' "practice styles" account for many of the differences observed in the care of patients with similar conditions *(1,2)*, and providing physicians with information about clinical results has been shown to reduce these variations considerably *(3)*. Wennberg and other investigators have noted that patterns of practice are more variable for those medical conditions whose outcomes are more controversial *(4,5,6,7)*.

NCHSR seeks to stimulate research designed to provide better guidance to clinicians about the outcomes and the costs of alternative practice patterns, and to identify feasible and acceptable methods for reducing variations due to factors such as physician convenience, perceptions about malpractice, peculiarities in payment schemes, or other considerations not related to the quality of care. Areas of particular interest include:

Model evaluations of patient outcomes

Studies are needed to assess the effectiveness of several medical treatments and surgical procedures which vary greatly in use among Medicare beneficiaries in different communities and which are important in terms of frequency of utilization, length of hospitalization, costs, and risks to the patient.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES · Public Health Service

To determine the feasibility and usefulness of research using current methods and measures, two approaches will be explored:

- Evaluations of the outcomes and costs of three or four surgical, medical, or diagnostic procedures, using a variety of technology assessment methodologies, including literature review, analysis of morbidity and mortality as measured by large claims data systems, and assessment of functional status of patients before and after treatment. Both prospective and retrospective studies are encouraged. Topics for study may be any of the treatments or procedures which are frequently used with Medicare beneficiaries, vary greatly in frequency of use from one community to another, and have not been carefully evaluated in terms of patient outcomes. Examples include prostatectomy, cholecystectomy, lens extractions, or endoscopic procedures. These studies are intended to provide better information about the probabilities of given outcomes and about the differences in results and costs associated with different patterns of medical practice.
- Examinations of the role of clinical data banks in evaluating, in terms of costs and patient outcomes, particular patterns of diagnosis and treatment in specific clinical settings. Randomized controlled clinical trials are not acceptable or affordable approaches for comparing different intensive care units or surgical services, for example, or for determining the long-term results of treatments for chronic diseases such as arthritis or multiple sclerosis. Clinical data banks have been useful in such situations for examining accumulated experience, but more testing is needed to determine whether the results of such non-experimental studies can be relied on for comparing the effectiveness or costs of different treatments or different institutions. In addition to determining the value of this approach to complex but important problems, these studies are directed toward refining the statistical and methodological techniques needed to carry out the analyses.

Assessments of admission and treatment criteria

Many commonly used treatments and diagnostic procedures have not been critically examined, and there is controversy and uncertainty among health care professionals concerning their value. Disagreements exist about the safest and most appropriate settings for providing many treatments or procedures, which may help to explain why the rates of use of hospitals for most medical conditions and for minor surgery vary widely from one community to another. A mature program of outcomes research requires accurate knowledge about the extent and the consequences of disagreement in these areas, as well as assessments of the evidence supporting the conflicting opinions.

- Outcomes research in these areas will involve empirical validation of the effectiveness of guidelines developed to reduce variation. These studies should begin with systematic reviews of the professional literature and of current patterns of medical practice, to identify critical points at which these disagreements affect the Medicare program significantly. Appropriate statistical and epidemiologic techniques should be employed to examine information concerning areas of significant disagreement about the efficacy of alternative treatments and procedures, and methods such as those of decision analysis used to estimate outcome probabilities for competing approaches. Similarly, differences in the process physicians use to decide whether to hospitalize Medicare patients should be explored. Evidence concerning the relationships between various admission criteria and patient outcomes sought may be obtained both through systematic review of the scientific literature and examination of comprehensive patient information systems. This information may enable expert panels to review the accumulated evidence and draft guidelines for Medicare beneficiaries concerning the appropriate use of treatments and procedures, and the need for hospitalization.

Improvements in research methods and data sources

Investigations into the effects of different medical practice patterns on patient outcomes require the identification and testing of more complete and accurate data sources, more powerful study designs, and more efficient analysis techniques. Research needs in this area include:

- Use of Medicare claims data system to study patient outcomes (including the integration of enrollment, hospitalization, and physician claims files).
- Development of more sensitive and comprehensive measures of patient outcomes, including functional status and quality of life.

- Formulation of better methods to identify and compare the costs of treatments and procedures for Medicare beneficiaries.
- Development of more efficient ways to estimate the boundaries of appropriate geographic areas and the size and socioeconomic characteristics of relevant populations.

Other increasingly important topics include:

- Examinations of the factors associated with variations in medical practice patterns, including clinical or epidemiologic correlates, organizational and administrative relationships, or reimbursement practices.
- Investigations into the generalizability of the variations identified: for example, is the level of variation a characteristic of an institution, organization, provider, procedure or treatment, medical specialty, geographic area, or payment method?
- Explorations of any unanticipated effects of altering the patterns of medical practice, such as changes in malpractice standards, role responsibilities, educational methods, organizational relationships, or personnel needs.
- Experimental investigations, including randomized controlled clinical trials as needed, into those practice patterns important to the Medicare program for which patient outcome studies produce incomplete or conflicting results.

Application procedures

Investigators are encouraged to discuss research ideas with NCHSR staff members prior to submitting a proposal. Additionally, staff members can offer suggestions about whether support should be requested through the usual NCHSR grants program or through the Small Grants Program. They should be contacted through:

Director
NCHSR Division of Extramural Research
18A-19 Parklawn Building
Rockville, MD 20857; 301/443-2345.

Grants are awarded for investigator-initiated projects in health services research at colleges and universities and other nonprofit organizations. NCHSR requires the use of Form PHS 398, Grant Application (also used by the National Institutes of Health). A grant application kit may be obtained from:

NCHSR Review and Advisory Services Program
18A-20 Parklawn Building
Rockville, MD 20857; 301/443-3091

Applications from State and local governments should be submitted on Form PHS 5161-1, Application for Federal Assistance (Nonconstruction Programs). These forms may be obtained either from NCHSR or the Division of Research Grants, NIH, at the address shown below.

All NCHSR research grant applications are reviewed by non-Federal experts for scientific and technical merit. Proposals for outcomes research which request more than $50,000 in direct costs may require approval by the National Advisory Council on Health Care Technology Assessment before funding decisions are made. The submission and review schedule is:

NIH/DRC submission	Study section review	Council review	Earliest start
June 1	October	February	March 1
October 1	March	June	July 1
February 1	June	September	September 30

Completed applications are to be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Ave.
Bethesda, MD 20250.

State and local government applicants must submit an original and two copies of the application; others are required to submit an original and six copies. Type "NCHSR" in item 2 on the face page of the application (PHS 398). An additional copy of all applications should be sent to the NCHSR Director of Extramural Research.

NCHSR's Small Grants Program provides support during fiscal year 1987 for innovative approaches to significant problems in the delivery of health services, encourages well designed descriptive and exploratory studies and pilot projects, and fosters the design and testing of new research methods and techniques. A particular advantage of this program for the investigator is the shorter period for proposal review compared with conventional grants. NCHSR will accept a Small Grant proposal anytime, and because of the modified review process, is able to obtain a recommendation from peer reviewers within about 90 days of receiving the proposal. NCHSR will notify applicants of funding decisions within another 30 days.

Applications submitted for review under the Small Grants Program are limited to a project period of two years and may not exceed $50,000 in total direct costs for the entire project period. Application materials are available from:

Chief, Review and Advisory Services Program
(Small Grants)
National Center for Health Services Research
and Health Care Technology Assessment
18A-20 Parklawn Building
Rockville, MD 20857; 301/443-3091

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COMMUNICATIONS

STATEMENT FOR THE RECORD
submitted by
THE AMERICAN COLLEGE OF PHYSICIANS
to the
SENATE FINANCE COMMITTEE, SUBCOMMITTEE ON HEALTH
July 11, 1988

The American College of Physicians, representing 65,000 physicians specializing in internal medicine, takes this opportunity to express support for S. 2182, an amendment to Title XVIII of the Social Security Act, which would increase the authorization for the patient outcome assessment research program. The College commends Senator Mitchell and the co-sponsors for introducing this important and timely legislation.

Efforts to assess the efficacy of medical interventions and measure the quality of care may have reached a "critical mass" that will yield significant progress in the next several years. These efforts build on the pioneering work of Drs. Wennberg, Brooks, Eddy, and others, and now include initiatives such as the clinical indicators project of the Joint Commission on the Accreditation of Healthcare Organizations and the quality assurance study of the Institute of Medicine.

The federal government can and should play a key role in generating research on medical outcomes. With expenditures approaching $100 billion for Medicare alone, it is unacceptable that the federal government devotes no more than a few million dollars to research on the effectiveness of the medical interventions for which it is paying.

We suggest that new funding which would be authorized by this legislation should be devoted, at least at the outset, to research on how to conduct studies that relate medical services and procedures to patient outcomes. The American College of Physicians has developed a methodology for these assessments, and others have used different approaches. A first priority for research should be development and evaluation of alternative methodologies for measuring outcomes and relating interventions to those outcomes. In a sense, the distinction is between basic research and applied research, and we suggest that the first role for an expanded government activity should be in basic research.

The College is eager to assist in developing these initiatives and to lend our expertise in this area. Since the late 1970's, we have been engaged in the evaluation of medical services and technologies and the development of practice guidelines that reflect the best medical judgment on appropriate utilization. This ongoing initiative is now known as the Clinical Efficacy Assessment Project (CEAP).

The essence of this activity is to bring the best scientific information available to the question of which interventions are effective and which are inappropriate or obsolete, under what circumstances they are appropriately utilized, and when they are unnecessary or of no benefit. Our studies give us a scientifically-derived benchmark on indications for use, that may in turn guide decisions on appropriate levels of utilization.

The CEAP studies range from assessments of a particular technology in all of its uses (e.g., the uses of intravenous pyelograms), to assessments of diagnostic testing in a specific clinical circumstance (e.g., testing after an acute myocardial infarction), to assessments of alternative approaches to studying an anatomic area (e.g., how to study the gall bladder). The studies consist of detailed review and synthesis of the literature, backed up by comprehensive review by experts within and outside of the College. Various techniques such as meta-analysis, decision analysis, and Bayesian probability assessments may be applied to the published data in order to develop practice guidelines.

Two documents are produced in a CEAP assessment: a detailed review of the literature in the form of a background paper, and a policy statement which is a short summary of the background paper and the clinical practice recommendations which emerge from it. The documents include a description of the technology, its safety, data regarding its efficacy and effectiveness, indications and contra-indications for use, data on cost, and conclusions and recommendations for appropriate use. The policy statement, but not the background paper, is subject to review and approval in the College governance structure, a process culminating in formal adoption as College policy by our Board of Regents.

We should not give the impression that this is an easy task, or that using technology assessment to derive clinical guidelines is an exact science easily applicable to all medical technologies. Obviously it is a task complicated by all the factors that make medicine art as much as science, whose practice allows for reasonable and honest individuals to differ about what constitutes effective intervention under widely varying circumstances. Therefore, practice guidelines derived from this research must always be applied with care and flexibility to take into account the experience and styles of its practitioners and the complexities of different patients in different circumstances.

Finally, if the Finance Committee reports S. 2182, we urge you to include in the report language a recommendation that research which is funded under this authority include an assessment of outcomes in the ambulatory setting. Most of the research conducted to date has focused on inpatient services, partly because the data has been available in academic centers and partly because those are the high-cost services. With more and more care provided outside the hospital, we must begin to study the relationship of medical interventions to patient outcomes in the ambulatory setting.

As a first step, and an action which can be taken under existing authority, we urge the Committee to ask House and Senate colleagues on the Appropriations Committees to fund this research in FY 1989 at the higher level recommended by the Senate. As a second and more long-term step, we urge you to report and pass S. 2182.

Statement of the
American Urological Association, Inc.

The American Urological Association recognizes the importance of rigorous, scientific review of medical and surgical procedures. Analysis of patient outcomes is an important component of this evaluation. Physicians, patients, third party payors and health policy makers all have legitimate interests in assuring that medicine is practiced effectively, appropriately and efficiently.

AUA believes that it is essential that the medical profession take the lead in assuring that care provided to patients is of the highest quality. such assessments. For that reason AUA developed standards for urologic care for use by physicians. Those standards will undergo a major review and revision beginning this Fall. Indications for treatment of the major urologic diseases will be studied and modified, if needed. Prostatism will, of course, be part of that assessment.

Prostate surgery has already been subject to Congressional scrutiny. Medicare payment rates were reduced by Congress in 1987 for transurethral resection of the prostate (TURP) and for open prostatectomy. These are the two procedures currently in use for treating prostatic enlargement. Since prostatic enlargement is common among older men, it should come as no surprise that prostatectomy is the second most common surgical procedure under Medicare.

In addition to this Congressional scrutiny, prostatectomy has been subject to critical review in the medical literature. Most notable has been a series of articles in the Journal of the American Medical Association by John E. Wennberg, M.D., et. al

(JAMA, May 27, 1988, Vol. 259, No. 20, p. 3010, p. 3018 and p. 3027). Because of the importance of prostate surgery to older men and to urologists, AUA believes it is important to respond to these analyses. More recent studies contradict some of the findings in these articles and AUA believes the Committee should have the benefit of that information before any decisions are made that could affect the quality and availability of urologic care.

Before reviewing that data it is useful to look at why the procedure is performed and the reasons for the relatively high number of procedures.

All men have a prostate gland and as men age most of them experience growth in that gland. What causes the enlargement is not clearly understood. The longer a man lives, the more likely he is to experience problems associated with that growth. As the prostate enlarges, it spreads, tightens around the urethra like a clamp around a garden hose and interrupts urine flow. Surgical intervention relieves this problem, but if untreated, it can damage the bladder and kidneys. Prevention of other conditions is an important aspect of this surgery. Treating kidney failure is more difficult and expensive than performing prostate surgery. Timely surgical intervention prevents these complications from occurring

Because men are living longer, prostate problems are becoming as common as gray hair and balding. Relief of symptoms and prevention of bladder and kidney damage is the goal of the urologic surgeon. Unlike some other medical conditions, there is currently no alternative treatment to surgery. Although other treatment modalities, such as pharmaceuticals, are being tested, none has reached the point of proven safety and efficacy.

Once the process of enlargement begins, the issue is not what to do but when to do it. For most men who live long enough, the enlargement will cause discomfort and other problems that can only be relieved by surgery. The question for the surgeon is when is the most appropriate time to perform the surgery.

Indications for surgery will vary somewhat from patient to patient, but in general, urologists agree that certain indications always require surgical intervention. These include urinary retention, when the blockage has become so severe that the patient can no longer urinate and will die if surgery is not performed. A second indication would be frequent urinary bleeding or urinary infection resulting from the enlarged prostate. The other, more common indications for surgery are the presence of symptoms of urinary disruption. This generally means that the patient is experiencing discomfort in urination, frequent urination, or other alteration of normal urinary function. The decision to operate depends upon the severity of this disruptive pattern. For some people, it may occur early in the growth of the prostate with obstruction resulting from a relatively small gland. Other men may not experience these symptoms until the gland has gotten quite large. The degree of disruption to life caused by these symptoms is very important in determining when surgery will be performed. Some patients insist that the surgery be performed immediately to relieve them of an uncomfortable and embarrassing condition that they can no longer tolerate. Clearly, each man will differ in his ability to tolerate these symptoms and surgeons may differ in their judgment as to when the symptoms warrant surgery.

Thus we see that volume of these surgical procedures is not a factor of "unnecessary surgery". If the pattern of enlargement and urinary disruption is present, surgery is almost inevitable. Undue delay in surgery can lead to complications of the bladder and kidneys that are permanent. Recent studies confirm what urologists have known for a long time -- patients who wait the longest to have surgery have the greatest chance of having poorer results.

The American Urological Association has published standards for various urologic procedures, including prostate surgery, and the indications for their performance. Adherence to these standards and effective utilization review in the hospital are ways to keep volume at appropriate levels. Congress has already directed the PROs to have mandatory preadmission review and possible second opinions for a number of high volume procedures. Prostate surgery will probably be one of the procedures on the list. Thus, utilization review will be broadly applied and inappropriate procedures should be eliminated.

A distinction should be made between the transurethral resection of the prostate and the suprapubic or open prostatectomy. Although TURP is the preferred procedure for many reasons, the choice of procedure by the surgeon is based largely on the gland size. A larger gland, perhaps 65 grams or over, is going to be removed by most surgeons using the open procedure. This is a function of the time it takes to perform a TURP for most surgeons on a gland of that size. Physician and patient fatigue becomes a very real factor in those circumstances. For the large gland, the open procedure is much quicker for the surgeon and less fatiguing for all parties. Nonetheless, the open procedure is substantially more expensive in its overall cost because the length of hospital stay for the patient who has had the open procedures is, on the average, twice as long as that of the TURP patient. This argues for early intervention so that the TURP can be performed safely, and the patient can then get out of the hospital in three or four days rather than eight or nine. Most urologists are making an effort to intervene surgically at a time when the TURP can be performed effectively, thus sparing the patient the rigors of open surgery and the costs of a long hospital stay. Probably 95% of prostatectomies are TURPs.

Thus, TURP is clearly the preferable procedure and has been so for many years. First introduced in the 1920's, TURP gained wide acceptance among urologists many years ago. The procedure is largely unchanged since then. Equipment improvements have occurred, most notably in the optics, but there have been no dramatic breakthroughs in technology, comparable to cataract surgery for example. The surgical skills needed have remained unchanged for many years.

Done properly, a TURP looks like a very smooth procedure. In the hands of a skilled urologist, it should be so, since he or she has had extensive training. Incidentally, educators in urology generally agree that the TURP is a difficult procedure to teach and probably the most difficult urological procedure to learn. Even though the procedure may appear relatively simple, it is not. It is major surgery, with all of the attendant risks to the patient if not done right. In fact, patients often need to be reminded that they have had major surgery and that recovery takes time.

In response to the Congressional action on Medicare payment for prostatectomy, AUA commissioned two studies of urology practice, focusing on TURP. The first was a mail survey of all 7700 urologists in practice in the United States, conducted by Multinational Business Services, Inc. (Survey of Practicing Urologists: Summer, 1980). The second was a study of 3885 patients (Mebust WK, Holtgrewe HL, Cockett ATK, Peters PC: Transurethral Prostatectomy Immediate and Postoperative Complications: A Cooperative Study of Thirteen Participating Institutions Evaluating 3,885 Patients; accepted for publication

J Urol) that specifically examined the morbidity and mortality associated with TURP.

The questions in the MBS survey instrument were not only reviewed by urologists, but also by staff at the Health Care Financing Administration, the Office of Management and Budget, the Physician Payment Review Commission. Their input certainly made it a more effective survey instrument.

MBS surveyed practicing urologists in the United States with particular focus on TURP. Using a list of urologists provided by the American Medical Association, 7,744 surveys were mailed on July 10, 1987. By September 11, 2,817 responses, or 36.4 percent, had been received. This is a large enough sample for the information to be statistically sound.

Over 90 percent of the respondents indicated that they are Board certified in urology. Their primary professional responsibility is care of the urologic patient. Caring for men with prostatism constitutes approximately 26 percent of their patient care workload. Most of their remaining professional time is spent in other urologic care for men and women. Thus, the respondents to the MBS questionnaire were experts in the subject of the survey. The answers they provided reflect their specialized expertise.

AUA learned several interesting facts about TURP as a result of this survey.

1. The incidence of TURP in a region does not appear to correlate with the number of urologists in the region. A higher number of urologists does not appear to lead to a higher incidence of prostate surgery. Nor is the converse true.

2. The number of prostatectomies performed each year appears to be reasonably stable. Information taken from the 1984-1986 MEDPAR File, and presented in 1987 to the Prospective Payment Assessment Commission by its staff, shows only a 2 percent variation in the volume of TURPS performed over the three-year period.

3. Urologists agree that TURP is the most difficult urologic procedure to learn and is much more difficult to learn and perform than the open procedure.

4. The TURP is a remarkably safe operation when performed by the skilled urologist. Mortality and morbidity rates are extremely low. Both studies confirm this fact.

5. The Medicare patient frequently has co-existing medical problems that complicate patient management. Thus, the urologist must be alert to, and must adapt to, the special medical needs of the elderly patient.

The other study looked at 3,885 consecutive TURP cases at 13 locations around the country and evaluated 250 parameters for each case. Approximately two-thirds of the procedures were performed on patients over 65 and approximately one-third of the patients were under 65. As a baseline, the authors used a benchmark study on TURP that had been done at the University of Kansas in 1961. It was important to look at work that was pre-Medicare to determine if the Medicare program was having any influence on surgeons' behavior. In the case of TURP, the reviewers were unable to determine that it has influenced physician behavior in any significant way. In addition to the points already made, the following was learned from the study.

1. The average age of TURP patients then and now is 69.

2. The average size of the gland resected then and now is 22 grams.

3. Eighty-one percent of all cases are now completed within 90 minutes or less. In 1961, 70 percent of cases were finished in that time. Much of this change is due to better training in urologic problems. Improvements in equipment, particularly the optics, has also increased the speed of the surgery thus permitting the resection of larger glands. This means that more men are able to have a TURP, rather than open surgery, thus avoiding the longer length of stay associated with open surgery.

In conclusion, AUA would like to make several points about the recent work by Dr. Wennberg that are at variance to the findings of AUA's own study.

First, the mortality and morbidity rates that Dr. Wennberg reports are far higher than any other reported in the scientific literature in the last 30 years. The most recent study cited in this testimony confirms the earlier conclusions that mortality and morbidity associated with TURP is extremely low (mortality 0.2% and immediate postoperative morbidity, 18%). In fact, recent data shows that mortality and morbidity figures have improved compared to scientific studies of 25 and 30 years ago. Although TURP is a major surgical procedure, AUA does not believe it carries the level of risk Dr. Wennberg associates with it. Patients should not defer surgery because of fears of harm stemming from the procedure. AUA believes that more harm can be caused by delaying the surgery than by performing it. In fact, patients who have waited the longest to have surgery often have the poorest result.

Contrary to the suggestion in Dr. Wennberg's publications that prostatectomies are performed primarily for the relief of symptoms, the cooperative study found that 70% of the 3,885 cases had multiple indications for surgery. Surgery primarily to relieve symptoms was performed in only 30% of the cooperative study's cases. While relief of symptoms is an improvement of the quality of life and is an important aspect to this surgery, it is clear that the need for surgery is usually based on other considerations, in addition to relief of symptoms.

Dr. Wennberg, in one recent analysis, has suggested "watchful waiting" over immediate surgery. There is no question that a physician may advise waiting to a patient whose symptoms are moderate until a more appropriate time to perform the surgery. If such waiting is done under the regular monitoring of a qualified urologist, it is an appropriate medical step. However, too often "watchful waiting" simply means the patient is tolerating symptoms as best he can and is not seeking medical care. This means that damage to the bladder and kidneys can be occurring in the absence of any medical intervention. This damage is probably irreparable. It is the avoidance of such damage that prompts surgical intervention.

The cooperative study of 3885 TURP cases reveals very clearly that patients who have the poorest surgical outcome are those who have delayed having surgery the longest. The results among black men were much poorer than those for white males. AUA believes this is the case because access to timely medical intervention is not available for many black males. Therefore, they are not presenting themselves for medical treatment until the symptoms have become acute (such as retention) and surgery is essential. Thus, advocating "watchful waiting" in lieu of surgical intervention is good advice only to the extent that the waiting is indeed watchful, under the care of a qualified urologist, and the patient is informed of the risks of delaying surgical intervention.

Dr. Wennberg suggests a re-examination of the advantages of open surgery vs. TURP. The open procedure has been largely abandoned in this country because the TURP is far preferable to the patient. The length of stay in the hospital is much shorter, the mortality and morbidity associated with TURP are less, and the results good. Thus, even though the operation is more difficult for the surgeon to perform, the TURP is the procedure of choice. AUA believes that most men would prefer 2-3 days in the hospital with no incision to 9 days in the hospital with a major incision and with the risks that are attendant to open surgery.

Finally, AUA would caution that Dr. Wennberg's statistics on impotence resulting from TURP must be examined closely. Impotence is often a very subjective determination by the patient and it is frequently difficult for the urologist to evaluate whether the impotence is associated with the surgery or with other factors. Clearly a responsible urologist will discuss all of these factors with the patient in helping him make the appropriate choice of treatment and timing; however, AUA believes it is unwise to focus heavily on these negative outcomes, particularly with these rather inflated numbers, since that could needlessly deter some men from seeking care on a timely basis.

AUA believes that it is appropriate for Dr. Wennberg and others to call attention to variations in practice and to analyze the outcomes of various procedures. We welcome the opportunity to participate in the dialogue and debate over these surgical procedures. However, we believe his focus on prostatectomy is not as rigorous and sound as it should be. We believe his data, some of it almost 20 years old, is contradicted by other, broader scientific analyses. AUA strongly recommends that Congress, the Health Care Financing Administration and other policymakers not make decisions about Medicare payment policies regarding these procedures until further evaluation can be made. The contradictions in data presented to the Subcommittee argue cogently for additional research and deliberation to assure that patient care is in no way disrupted.

A/S/G/E the AMERICAN SOCIETY for GASTROINTESTINAL ENDOSCOPY

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July 19, 1988

The Honorable George J. Mitchell
Chairman
Subcommittee on Health
Committee on Finance
The United States Senate
SD-205 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Mitchell:

The American Society for Gastrointestinal Endoscopy (ASGE) applauds your leadership in introducing legislation to encourage more research into the outcomes of medical procedures and also in holding the hearing on July 11th to receive testimony on the current status of outcomes research. ASGE believes that outcomes research is an important area for investigation and encourages the government to work closely with the physician community to develop research protocols and projects.

We believe that one important part of outcomes research is the development of meaningful standards for the use of medical and surgical procedures. As specialists in endoscopy, the members of ASGE have been particularly concerned that, as this technology evolves, a consensus be reached on its appropriate uses.

For your information, I am pleased to submit three ASGE publications which we believe you will find of interest. The first is a document entitled, "Appropriate Use of Gastrointestinal Endoscopy," which is a consensus statement on the indications for use of these procedures. The second is entitled, "Therapeutic Gastrointestinal Endoscopy," and provides information on the emerging use of endoscopy for therapeutic purposes. The final document is the May/June 1988 addition of "Gastrointestinal Endoscopy," ASGE's official journal, which contains a series of statements and guidelines developed by ASGE on training for endoscopy and the role of endoscopy in a number of medical conditions. I request that this material be made part of the official hearing record of the Subcommittee.

Should you or other members of the Subcommittee have questions about this material, please feel free to contact our headquarters office.

Your thoughtful leadership in health policy is appreciated by all members of ASGE. We are very interested in your efforts and look forward to the opportunity to work with you and other members of the Subcommittee on issues of interest and concern.

Sincerely,

Walter J. Hogan
Walter J. Hogan, M.D.

Appropriate Use of Gastrointestinal Endoscopy

A consensus statement from the
American Society for Gastrointestinal
Endoscopy. Prepared by the
Committee on Endoscopic Utilization.
Reviewed and approved by the
Standards of Training and Practice
Committee and by the Governing Board.

June 1986

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Introduction

During the past 15 years a genuine diagnostic revolution has occurred in which developments in fiberoptics have drastically altered the approach to patients with gastrointestinal problems. Important therapeutic applications have evolved as well. The effectiveness and safety of procedures done by trained persons has been demonstrated. Much has been learned about disease from endoscopic observations. Fiberoptic procedures have become more accurate, and are therefore more frequently employed in management decisions. Over one million gastrointestinal fiberoptic procedures are performed annually in the United States.

This period of expanding endoscopic use has not been consistently monitored. ***Indications*** for procedures have evolved as guidelines through the American Society for Gastrointestinal Endoscopy (ASGE), but the frequency or uniformity of their use is unknown. ***Standards of training and practice*** have been developed, but their influence in granting endoscopic privileges is unclear. Minimal standards for initial competence and for maintaining skills have not been defined or tested; and while evidence of training and experience may be required by local hospital governance, general credentialing standards are neither available nor in use.

The ASGE has prepared and distributed many consensus guidelines statements on the indications for endoscopic procedures in the management of various gastrointestinal disease states. These guidelines have been very carefully developed, reviewed by several thousand gastroenterologists and approved by the governing boards of the ASGE, The American Gastroenterological Association (AGA), and the American College of Gastroenterology (ACG). Similarly, statements on endoscopic training and on standards of practice have been prepared with the approval of these three societies and of the Society for Surgery of the Alimentary Tract (SSAT). These guidelines have been made available to hospital staffs as aids in defining appropriate endoscopic practice and minimal training standards in hospitals or communities. Their influence on the processes of privilege-granting is unknown but is judged to have been significant.

The ASGE and others have recognized that standards of training and practice must be defined and implemented on a national, as well as a local basis, in order to ensure good patient care by appropriate use of gastrointestinal endoscopy. Therefore, the ASGE has had discussions with the Joint Commission on Accreditation of Hospitals (JCAH) concerning their mutual interest in quality of care and peer review mechanisms. The following information has been prepared for use by JCAH and by local hospital procedure review committees as they define standards of endoscopic practice and training. The indications statement will also be helpful to primary care physicians as they direct appropriate care for their patients.

Definition of Gastrointestinal (GI) Endoscopic Procedures

Esophagogastroduodenoscopy (EGD) affords an excellent view of all mucosal surfaces of the esophagus, stomach, and proximal duodenum. During ***colonoscopy*** the entire colon and rectum are examined. Standard ***diagnostic*** functions include inspection, biopsy and photography. Diagnostic observations are made concerning focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, motility, and extrinsic compression by contiguous structures. ***Therapeutic*** endoscopic procedures are varied and include removal of polyps or foreign bodies, and treatment of gastrointestinal bleeding.

Endoscopic retrograde cholangiopancreatography (ERCP) employs fiberoptic endoscopy to identify and cannulate the papilla of Vater in the duodenum, with resulting x-ray contrast opacification of the biliary tree and pancreatic ductal system for precise *diagnosis*. *Therapeutic* applications of ERCP techniques include endoscopic retrograde sphincterotomy (ERS) with or without stent placement for treatment of common bile duct obstruction by calculi, stricture or neoplasm.

Flexible fiberoptic sigmoidoscopy (FFS) employs a flexible instrument no longer than 65cm to examine the rectum, sigmoid, and a variable length of left colon. The examination is brief and requires simple preparation with two enemas, whereas colonoscopy requires preparation of the entire colon. FFS is usually employed for screening asymptomatic patients for early polyps or colorectal cancer, and is not a substitute for colonoscopy.

A Summary Statement on Endoscopic Training and Practice

The ASGE supports the following statements pertaining to endoscopic training and practice. A more detailed statement is available in the ASGE *Statement on Endoscopic Training*.

1. Those performing gastrointestinal endoscopy should be well-trained in endoscopy as part of a broader clinical discipline such as gastroenterology, gastrointestinal surgery, or colorectal surgery.

2. Training is usually acquired during formal residency/fellowship training. Training will include integration of endoscopy with clinical problem-solving and hands-on performance of procedures under direct supervision of an experienced endoscopic trainer.

3. Endoscopic training acquired outside residency/fellowship training programs will be *equivalent* to that provided in formal training programs.

4. Endoscopic competence is determined and certified by the endoscopy training supervisor.

5. Endoscopic competence will be demonstrated by those seeking privileges in local hospitals.

6. Endoscopic privileges should not be granted to applicants citing attendance in short courses as the sole training experience.

7. Privileges should be granted for each *separate* procedure for which training has been documented and competence verified. The ability to perform any one endoscopic procedure does not imply competency to perform others.

8. Training requirements for flexible fiberoptic sigmoidoscopy (FFS) are less than those for other gastrointestinal endoscopic procedures. Nevertheless, some training to include supervised hands-on experience is necessary. Documented competence will precede granting of privileges in FFS.

9. Endoscopic privileges will be reviewed periodically with due consideration to procedure performance and continuing education.

Endoscopic Privilege Granting

Local hospital committees wishing to apply the foregoing criteria may find the following questions helpful in their credentialing process:

1. Has the hospital staff developed minimal standards of endoscopic training and performance which are uniformly applied to all endoscopists?

2. Are privileges granted to physicians with formal training in endoscopy *and* related clinical disciplines?

    A. Did the endoscopic training combine interpretive and cognitive experience with acquisition of technical skills?

    B. Did the applicant provide evidence of a supervised training program experience with documentation of competence by the endoscopy training supervisor?

    C. Were minimal numbers of supervised procedures demonstrated (e.g., EGD 50-75; colonoscopy 50; polypectomy 15; ERCP 35-50)?

    D. Was there demonstration of competence prior to full credentialing?

3. Are privileges granted to physicians trained outside a formal endoscopy training program? If so:

    A. Was the training equivalent to a formal program?

    B. Was endoscopy integrated with clinical problem-solving?

    C. Was there actual hands-on performance of endoscopy under direct supervision of an experienced endoscopic trainer?

    D. Were minimal numbers of supervised procedures demonstrated?

    E. Was competence demonstrated prior to granting privileges?

4. Are endoscopic short courses unacceptable as the only evidence of competence for granting of privileges?

5. Are privileges granted on a procedure-specific basis such as EGD, colonoscopy, ERCP or ERS?

6. Are there established training requirements for the performance of FFS by nonendoscopists? Although training for FFS is less rigorous than that for colonoscopy, some supervised hands-on experience is necessary. Based on published accounts of training experience for nonendoscopists, 7-10 supervised exams are necessary to learn minimal competence with 35cm FFS, and 15-30 are required for 65cm FFS.

7. In the process used for renewal of privileges, is ongoing review of procedure performance utilized and is some minimal continuing experience required?

8. Is it recognized that new procedures often require new training? Depending on how major a variant the new procedure is from established techniques for which an individual already has credentials, additional supervised training with documentation of competence may be required. For example, competence in ERCP requires additional training and supervised hands-on experience even for those with extensive experience with EGD and colonoscopy.

9. Is it clear that subspecialty board certification or membership in regional or national societies does not, per se, indicate competence to perform GI endoscopic procedures?

Indications for Gastrointestinal Endoscopy

Introduction

The goals for performing ***diagnostic*** gastrointestinal endoscopy are to visually examine the entire organ or duct system under study, to discover all significant abnormalities, and to remove or biopsy lesions as appropriate. Unnecessary repetitive procedures should be avoided.

The goals of performing safe and successful ***therapeutic*** gastrointestinal endoscopy are to manage continuing bleeding, remove neoplastic polyps or foreign bodies, and to remove obstruction due to stricture, malignancy, or gallstones.

The indications and nonindications for doing each of the endoscopic diagnostic procedures are listed on the following pages. These guidelines are based on a critical review of available information and on broad clinical consensus, and are as specific and definitive as possible.

Clinical considerations may occasionally justify a course of action at variance with these recommendations. Such occasional indications, however, are not part of usual or frequent practice.

General Indications Statements

GI Endoscopy is Generally Indicated:

A. If a change in management is probable or is being considered based on results of endoscopy

B. After an unsuccessful trial of therapy, as when functional or uncomplicated acid-peptic causes are suspected

C. Often as the initial method of evaluation as an alternative to x-ray studies

GI Endoscopy is Generally Not Indicated:

A. When the results of study will not contribute to a management choice

B. For periodic follow-up of healed benign disease unless surveillance for premalignant conditions is planned

GI Endoscopy is Generally Contraindicated:

A. When the risks to patient health or life are judged to outweigh the most favorable benefits of the procedure

B. When adequate patient cooperation cannot be obtained

C. When a perforated viscus is known or suspected

Specific Indications Statements

1. Esophagogastroduodenoscopy (EGD) is Generally Indicated for Evaluating:

A. Upper abdominal distress which persists despite an appropriate trial of therapy

B. Upper abdominal distress associated with signs suggesting serious organic disease (e.g., anorexia and weight loss)

C. Dysphagia or odynophagia

D. Esophageal reflux symptoms which are persistent or progressive despite appropriate therapy

E. Persistent vomiting of unknown cause

F. Other system disease in which the presence of upper GI pathology might modify other planned management. Examples include patients with: a history of GI bleeding who are scheduled for renal transplantation; long term anticoagulation; chronic nonsteroidal therapy for arthritis

G. X-ray findings of:
1. A neoplastic lesion, for confirmation and specific histologic diagnosis
2. Gastric or esophageal ulcer
3. Evidence of upper tract stricture or obstruction
4. Mass

H. Gastrointestinal bleeding:
1. As the first procedure in most actively bleeding patients
2. When surgical therapy is contemplated
3. When rebleeding occurs after acute self-limited blood loss
4. When portal hypertension or aorto-enteric fistula is suspected
5. For endoscopic therapy of upper gastrointestinal bleeding
6. For presumed chronic blood loss and iron deficiency anemia when colonoscopy is negative

EGD is Generally Not Indicated for Evaluating:

A. Distress which is chronic, nonprogressive, atypical for known organic disease, and is considered functional in origin (there are occasional exceptions in which an endoscopic examination may be done *once* to rule out organic disease, especially if symptoms are unresponsive to therapy)

B. Intermittent dyspepsia

C. Uncomplicated heartburn responding to medical therapy

D. Metastatic adenocarcinoma of unknown primary site when the results will not alter management

E. X-ray findings of:
1. Asymptomatic or uncomplicated sliding hiatus hernia
2. Uncomplicated duodenal bulb ulcer which has responded appropriately to therapy
3. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy

F. Patients without current gastrointestinal symptoms about to undergo elective surgery for non upper gastrointestinal disease

2. Sequential or Periodic EGD May Be Indicated:

A. In patients requiring periodic surveillance for proven Barrett's esophagus

B. For follow-up of selected large esophageal, gastric or stomal ulcers to demonstrate healing

C. In patients with prior adenomatous gastric polyps

Sequential or Periodic EGD is Generally Not Indicated For:

A. Surveillance for malignancy in patients with gastric atrophy, pernicious anemia, treated achalasia, or prior gastric operation

B. Surveillance of healed benign disease such as esophagitis, gastric or duodenal ulcer

C. Surveillance during chronic repeated dilations of benign strictures unless there is a change in status

Specific Indications Statements (Cont'd)

3. Colonoscopy is Generally Indicated in the Following Circumstances:

A. Evaluation of an abnormality on barium enema which is likely to be clinically significant, such as a filling defect or stricture

B. For discovery and excision of colonic polyps:
  1. When polyps are seen on barium enema x-ray
  2. When neoplastic polyps are detected by proctosigmoidoscopy

C. Evaluation of unexplained gastrointestinal bleeding
  1. Clinically significant hematochezia
  2. Melena with a negative upper GI work-up
  3. Presence of unexplained fecal occult blood

D. Unexplained iron deficiency anemia

E. Surveillance for colonic neoplasia
  1. Examination to "clear" entire colon of synchronous cancer or neoplastic polyps in a patient with a treatable cancer or neoplastic polyp
  2. Follow-up examination at 2-3 year intervals after resection of a colorectal cancer or neoplastic polyp and an adequate initial "clearing" colonoscopy
  3. Patients with a strongly positive family history of colon cancer
  4. In patients with chronic ulcerative colitis: Colonoscopy every 1-2 years with multiple biopsies for detection of cancer and dysplasia in patients with:
     a. Pancolitis of greater than seven years duration
     b. Left-sided colitis of over 15 years duration (no surveillance needed for disease limited to rectosigmoid)

F. Chronic inflammatory bowel disease of the colon if more precise diagnosis or determination of the extent of activity of disease will influence immediate management

G. Therapeutic colonoscopy, as control of bleeding or colonic decompression

Colonoscopy is Generally Not Indicated in the Following Circumstances:

A. Possible colon cancer when results will not alter management

B. Chronic, stable, irritable bowel syndrome; there are unusual exceptions in which a colonoscopy may be done *once* to rule out organic disease, especially if symptoms are unresponsive to therapy

C. Acute limited diarrhea

D. Metastatic adenocarcinoma of unknown primary site in the absence of colonic symptoms

E. Routine follow-up of inflammatory bowel disease (except for cancer surveillance in chronic ulcerative colitis)

F. Routine examination of the colon in patients about to undergo elective abdominal surgery for non-colonic disease

G. Upper GI bleeding, or melena with a demonstrated upper GI source

H. Postoperative follow-up after curative resection of a colon cancer solely to detect suture-line recurrence

I. Bright red rectal bleeding in a patient with a convincing anorectal source on sigmoidoscopy

J. Hyperplastic polyps

Colonoscopy is Generally Contraindicated In:

A. Fulminant colitis

B. Possible perforated viscus

C. Acute severe diverticulitis

Specific Indications Statements (Cont'd)

4. Endoscopic Retrograde Cholangiopancreatography (ERCP) is Generally Indicated In:

A. Evaluation of the jaundiced patient suspected of having treatable biliary obstruction

B. Evaluation of the patient without jaundice (with or without prior cholecystectomy) whose clinical presentation suggests bile duct disease

C. Therapeutic pancreatic or biliary endoscopy, e.g., endoscopic sphincterotomy, balloon dilatation of strictures, stent placement across strictures; these procedures frequently require follow-up endoscopy

D. Evaluation of signs or symptoms suggesting pancreatic malignancy when results of ultrasound (US) and/or computed tomography (CT) are equivocal or normal

E. Evaluation of recurrent or persistent pancreatitis of unknown etiology

F. Preoperative evaluation of the patient with chronic pancreatitis

G. Evaluation of possible pancreatic pseudocyst undetected by CT or US and for known pseudocyst prior to planned surgical therapy

ERCP is Generally Not Indicated In:

A. Evaluation of abdominal pain of obscure origin in the absence of objective findings or test results which suggest biliary tract or pancreatic disease

B. Evaluation of suspected gallbladder disease without evidence of bile duct disease

C. Evaluation of a single episode of acute pancreatitis without evidence of gallstone disease

D. As further evaluation of pancreatic malignancy which has been demonstrated by US or CT

5. Flexible Fiberoptic Sigmoidoscopy (FFS) is Generally Indicated For:

A. Screening of asymptomatic patients at risk for colon neoplasia

B. Evaluation of suspected distal colonic disease when there is no indication for colonoscopy

C. Evaluation of the entire colon in conjunction with barium enema x-rays

FFS is Generally Not Indicated:

A. When colonoscopy is indicated (see page 8)

B. For polypectomy, because colonoscopy is indicated and full colonic preparation is necessary to prevent explosions

FFS is Generally Contraindicated For:

A. Fulminant colitis

B. Severe acute diverticulitis

C. Peritonitis

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The Role of Percutaneous Endoscopic Gastrostomy in Enteral Feeding 35S

Infection Control during Gastrointestinal Endoscopy 37S

This is a series of statements discussing the use of gastrointestinal endoscopy in common clinical situations. The text has been prepared by the Standards of Training and Practice Committee of the American Society for Gastrointestinal Endoscopy, reviewed and approved by other physicians and surgeons with expertise in gastrointestinal endoscopy, and approved by the governing bodies of the American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association, the American College of Gastroenterology, the Society for Surgery of the Alimentary Tract, and/or the Society of American Gastrointestinal Endoscopic Surgeons as indicated on each statement.

Guidelines for the appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Controlled clinical studies are needed to clarify aspects of these statements, and revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance from these recommendations.

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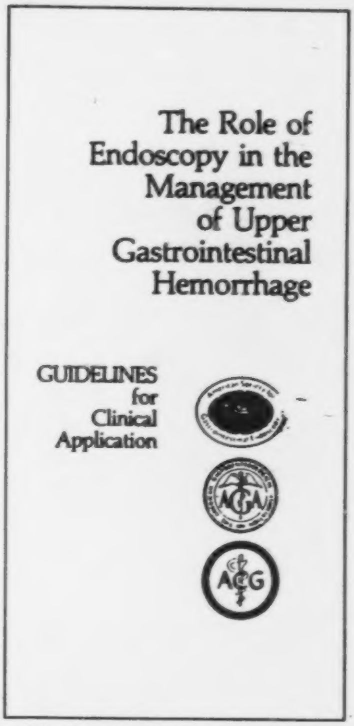
ASGE guidelines: introduction

This supplement to the *Journal* was created so that the guidelines and statements that have been prepared by the Standards of Training and Practice (STP) Committee of the American Society for Gastrointestinal Endoscopy (ASGE) could be published in a fashion that would allow them to be indexed and referenced. For several years the ASGE has produced and distributed these guidelines. A broad range of topics has been addressed, which could be generally categorized into three separate areas: (1) those topics dealing with a specific clinical-endoscopic matter (e.g., the role of colonoscopy in patients with inflammatory bowel disease); (2) those topics dealing with a general concern to all who perform gastrointestinal endoscopy (e.g., control of endoscopically transmitted infection); and (3) those topics clarifying the position of the Society on matters related to training and/or standards of practice (e.g., the role of the short course in endoscopic training).

By design, the topics selected are ones about which there is not universal agreement and the data are incomplete. By developing a consensus opinion based on a critical review of the existing data, committee discussion and interchange, and expert input, the guideline is produced. All of the guidelines contain important disclaimers underscoring that "controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear." They also emphasize that "clinical considerations may justify a course of action at variance from these recommendations."

The process by which a guideline is created is defined. First, an idea for a guideline is generated. It may come from the membership, the Governing Board, the STP Committee itself, or from someone corresponding with the Society. Once the topic is decided upon, the chairman of the STP Committee assigns one or more members of the committee to write a first draft. Often that individual has expertise in the area. The STP member presents the draft to the entire committee at one of its two yearly meetings. The member who prepares the draft will have critically reviewed the literature and spoken with experts on the subject. In a detailed fashion the committee dissects and reflects upon the draft, "cutting and pasting" as they go. If the committee believes that the guideline is near completion after a "first pass," the principal drafter makes the recommended modifications, and after the chairman "signs off" on it, it is forwarded to the Society's Governing Board. For some of the more difficult guidelines, it may be apparent that further out-of-committee work is required, in which case, the guideline is "tabled" until the next committee meeting. The Governing Board members give their input, and after those alterations are made, the document is circulated for review. This draft is sent to all ASGE



The Role of
Endoscopy in the
Management
of Upper
Gastrointestinal
Hemorrhage

GUIDELINES
for
Clinical
Application

Figure 1. Representative title page. This guideline is on the role of endoscopy in the management of upper gastrointestinal hemorrhage.

members, to appropriate committees and governing boards of other societies to whom this guideline would be relevant (e.g., American Gastroenterological Association, American College of Gastroenterology, Society for Surgery of the Alimentary Tract, and Society of American Gastrointestinal Endoscopic Surgeons), and to some national experts, soliciting their comments. These responses are directed to the chairman of the STP Committee, who, consulting with STP Committee members, considers this input and revises the document. The revised draft is then returned to the Governing Board for final approval, and then the guideline is published. Heretofore, the guideline has been published as a pamphlet (3¾ × 8⅝ inches in size), which is distributed directly to the membership and to others upon request.

Recently, the guidelines have taken a standardized form (Fig. 1). The title page clearly defines the subject matter. A separate color bar is used for each guideline. Within the color bar, there is a display of the imprimatur of the ASGE as well as those of other societies that have endorsed this particular guideline. On the inside cover is a generic statement discussing the preparation of this document and an explanation as to who has reviewed it. A disclaimer statement is also listed here. At the bottom of the page is the address to which requests for reprints should be forwarded. References to the body of the text are listed at the end of the document as well as the publication number and date.

Recently, the Governing Board has decided that it would be appropriate for these guidelines to be published in *Gastrointestinal Endoscopy*. This would ensure that the guidelines are indexed and therefore be more easily obtained and referenced. Publication in the *Journal* will also give them wider distribution. Some believe that they carry more weight if published in the *Journal* rather than existing only as pamphlets. Therefore, this supplement was created as a compendium of the previously published guidelines.

As new guidelines are developed or as older ones are revised, they will appear in regular editions of *Gastrointestinal Endoscopy*.

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Guidelines for establishment of gastrointestinal endoscopy areas

Safe and efficient performance of gastrointestinal endoscopy depends on the availability of (1) a properly trained gastrointestinal endoscopist,[1] (2) properly trained ancillary personnel, (3) functional modern equipment, and (4) an adequately furnished endoscopy area.

Guidelines and statements on endoscopic training and the standards of practice of gastrointestinal endoscopy have been published.[1,2] Training programs for gastrointestinal assistants are available.[3]

Rapid progress in the development of flexible fiberoptic instruments and accessories has introduced into clinical practice a great variety of instrument models. Contemporary, well maintained equipment is mandatory for examination of the gastrointestinal tract.

Whenever gastrointestinal endoscopic examinations are performed in the hospital, it is appropriate to designate a specific location as the endoscopy area. This area may serve other functions but must meet minimal requirements. The endoscopist who uses the area should work with hospital staff to assure the adequacy of personnel, facilities, and equipment. The size and detailed furnishings of the endoscopy area will depend on the volume and particular type of endoscopy performed. Capability for bedside endoscopy should be available for special situations.

If a special endoscopy area is not available, endoscopic procedures may be performed in the operating suite or emergency room until the volume of procedures warrants designation of a specific endoscopy area. When this area is established, the use of operating rooms is appropriate only for exceptional cases. General anesthesia or the presence of an anesthesiologist is rarely necessary for endoscopic procedures.

If the unit does not contain its own radiological facilities, it is desirable to locate the unit in or near the radiology department. When x-ray equipment is used during gastrointestinal procedures, radiologic safety standards should be observed.

Photographic equipment for documentation and a sidearm for a second observer are desirable. An endoscopic instrument cabinet is important for easy access and proper maintenance of the fiberoptic instruments. An adequate storage area for drugs, disinfecting materials, and ancillary equipment is essential. One or more sinks for personnel and instrument needs, as well as adequate toilet facilities, are required. An area for patient gowning and for waiting prior to procedure is desirable. Adequate arrangements should be made for transportation of medicated patients into and out of the unit, and a supervised area for postendoscopic observation should be available.

Cardiopulmonary resuscitation facilities for emergency use must be available and easily accessible in the hospital, as well as in the office setting. Both physicians and assistants should be versed in resuscitation. Regular maintenance is necessary to assure proper functioning of the emergency equipment at all times. Two independent suction devices are needed for the management of emergencies.

A safe, efficient electrocautery device is needed for the performance of electrosurgical procedures. The availability of a second compatible unit is desirable in case of breakdown. Standard procedures for establishment and maintenance of electrical safety must be followed.

When endoscopic examinations are performed in an outpatient or office setting, criteria for equipment, facilities, competency and training of staff, as well as documentation and record-keeping, should be similar to those used in a hospital. In addition, arrangements should be made for the transfer to and processing of pathologic specimens in a pathology laboratory. Esophagogastroduodenoscopy, colonoscopy, colonoscopic polypectomy, and dilatation of esophageal strictures can be performed safely in most instances in an outpatient or office facility. Endoscopic retrograde cholangiopancreatography and laparoscopy can also be performed as outpatient procedures in selected patients. However, the decision to perform inpatient vs outpatient endoscopy in a patient with an increased risk of morbidity should be individualized to that patient's clinical situation. With the increasing costs of inpatient care, every effort should be made to perform endoscopy on an outpatient basis when it is appropriate and when adequate facilities are available.

ASGE Publication No. 1003. Published 1980. Revised March 1986

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The role of endoscopy in the management of upper gastrointestinal hemorrhage

Guidelines for clinical application

The purpose of this statement is to provide a current, practical basis for the use of endoscopy in the management of patients with upper gastrointestinal hemorrhage.

For the purposes of these guidelines, upper gastrointestinal bleeding is considered in three categories: (1) Active hemorrhage, which may either be torrential or less severe. This is usually manifested by hematemesis or return of red or pink blood per nasogastric tube. Continuing transfusion requirements and evidence of hypovolemia are frequently seen with this group. (2) Acute, self-limited blood loss, in which cessation of active bleeding is presumed because there is hemodynamic stability and no evidence of continuing fresh blood loss. (3) Chronic bleeding occurring over weeks or months. The manifestations are usually those of occult bleeding or iron deficiency anemia. With these three categories, the problems of upper gastrointestinal bleeding may be approached differently with regard to endoscopic indications and urgency.

An upper gastrointestinal source may be presumed from historical details, the presence of hematemesis, or obvious blood in the nasogastric aspirate. Melena is usually, but not always, caused by an upper gastrointestinal lesion. On occasion, bright red blood per rectum may be the predominant manifestation of severe upper tract hemorrhage.

Successful endoscopy of the bleeding patient requires the skills of a well trained endoscopist and attention to special circumstances. Under these conditions, endoscopy is well tolerated, although complication rates are higher in the actively bleeding patient. There is no convincing evidence that endoscopy significantly provokes or initiates further bleeding.[1-3] Endoscopy can be technically performed in all but the few patients whose initial bleeding is so rapid that emergency measures are required for control.

The endoscopic examination should, when possible, provide information regarding: (1) location and identity of the bleeding source; (2) whether bleeding is continuing and rate of blood loss[4]; (3) whether bleeding is from an arterial source; (4) which of multiple lesions is the source of bleeding; (5) whether a vessel is visible in an ulcer base[5,6]; and (6) whether stigmata of recent hemorrhage are present.[2,6,7] These endoscopic observations relate to prognosis and influence therapeutic decisions.

Upper gastrointestinal endoscopy is a very accurate means of determining the presence and site of bleeding.[2,8] However, the beneficial effects of precise diagnosis on patient outcome are presently unclear. Although it seems reasonable to conclude that outcome is improved when therapy is guided by early precise delineation of the bleeding site, this has been neither proved nor disproved.[9-13] The following guidelines are proposed for the use of endoscopy in patients with upper gastrointestinal bleeding.

Urgent gastrointestinal endoscopy should be strongly considered in all patients with active hemorrhage (Category 1). Endoscopy should ideally be performed soon after the patient's hemodynamic status has been stabilized.[14] If surgery is contemplated in the actively bleeding patient, endoscopy may affect the decision to operate, the timing of the operation, and the kind of operation.[15] In such patients, endoscopy is very beneficial if it can be performed safely. Observation of the bleeding area (e.g., the esophagogastric junction, gastric body, or duodenal bulb) is clinically helpful even when visualization of the precise lesion is precluded by brisk bleeding or clots. Endoscopic complications are more likely to occur during urgent examination of seriously ill patients. Errors in interpretation of findings, which may result in inappropriate decision making, are also more likely to occur.

The timing of endoscopy as a diagnostic and potentially therapeutic procedure is usually less urgent in Category 2 patients since they are hemodynamically stable and without evidence of active, ongoing hemorrhage. There is a consensus opinion that early or emergency endoscopy is valuable in Category 2 patients with known liver disease,[16] with suspected portal hypertension, with suspected aortic-enteric fistula, and in patients with rebleeding after initial stabilization. The availability of endoscopic treatment modalities may also influence the decision as to whether or

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not early endoscopy should be done. If identification of the bleeding source seems appropriate, endoscopy is most accurately done within 24 hours of the bleeding episode.[2,4,14] Because of disadvantages of low diagnostic yield and interference with other diagnostic and potentially therapeutic studies, barium radiographs have no role in the early investigation of bleeding patients in Category 1 or 2.

The evaluation of chronic gastrointestinal blood loss (Category 3) often requires study of the entire gastrointestinal tract. The source of occult bleeding in asymptomatic patients is usually discovered in the colon.[17,18] An endoscopic search for upper gastrointestinal bleeding sites may be indicated by appropriate historical data, dyspepsia or other symptoms, evidence of anemia or persistent bleeding.

Although endoscopic therapy for upper gastrointestinal bleeding is still evolving, several effective methods have now been identified (e.g., variceal sclerotherapy, laser photocoagulation, electrocautery, and use of heater probe coagulation) which greatly increase the potential utility of upper endoscopy in patients with gastrointestinal hemorrhage.[19,20]

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The role of colonoscopy in the management of patients with colonic polyps

Guidelines for clinical application

The purpose of this statement is to provide a current, practical basis for the use of colonoscopy in patients with colonic polyps.

Most polyps seen during colonoscopy can be completely removed by electrocautery.[1-4] The safety of this procedure has been substantiated by the low incidence of complications reported in numerous series.[5-7] The endoscopist should be prepared to perform a total examination and remove all polyps found at the time of the first colonoscopy, although technical factors encountered during colonoscopy may limit completion of the procedure. Every effort should be made to avoid repetitive procedures.

The finding of a neoplastic polyp by rigid or flexible sigmoidoscopy is an indication for examination of the entire colon, since 30%-50% of such patients will harbor additional polyps. Biopsy-proven inflammatory colorectal polyps are not related to cancer.[8] It is not clear whether hyperplastic polyps are associated with a higher incidence of adenomatous polyps. Colonoscopy is the preferred method of examination because it allows resection of synchronous polyps. Although previously a common practice, performance of a barium enema is no longer considered a prerequisite to the safe and accurate performance of colonoscopy.

The morbidity, mortality, and cost of colonoscopic polypectomy are significantly less than polypectomy by laparotomy.[3,4] The latter is justified only when an experienced endoscopist is unable to safely remove the entire lesion.

Although controversy still exists regarding the degree of malignant potential of polypoid lesions of the colon, current opinion is that most cancers arise in preexisting neoplastic polyps.[9,10] It is impossible to tell grossly which lesions are or will become malignant. The incidence of malignancy in a polyp rises as the size and villous component of the polyp increase.[11] Because malignant changes in polyps are frequently missed by single and even multiple forceps biopsies, histologic evaluation should be based on examination of the completely excised polyp. In general, all polypoid lesions greater than 0.5 cm in diameter should be totally excised and recovered for histologic examination. The decision to perform colonoscopy for the purpose of removing polyps less than 0.5 cm in diameter must be individualized. Depending upon the patient's age, past history, and family history and the presence of other diseases, colonoscopic polypectomy may be recommended for removal of these small lesions.[4-7] Although the occurrence of carcinoma in a lesion under 0.5 cm is rare, it is reasonable to destroy or remove all such diminutive lesions as they are encountered at the time of colonoscopy for any indication. Representative biopsy samples may be obtained when these small lesions are too numerous for all of them to be removed.

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Large, benign-appearing sessile polyps have a high malignant potential and tend to recur locally for excision.[11] Therefore, a patient who has colonoscopic excision of these lesions should have repeat colonoscopy within 6 months to document complete removal. If residual polyp tissue is found, it should be removed if possible and the completeness of excision checked once again within another 6-month period. If complete removal of the lesion has been verified at the first or second follow-up interval, then subsequent surveillance colonoscopy is appropriate at 1- to 3-year intervals thereafter. If, however, a large benign-appearing sessile polyp cannot be completely or safely removed endoscopically within 1-3 examinations, then subsequent bowel resection is indicated.

Diagnostic colonoscopy for cancer surveillance is appropriate in certain high risk patients. Risk factors include longstanding ulcerative colitis, familial cancer syndromes, or personal history of colorectal neoplastic polyps or cancer.[12] Colonoscopy for cancer surveillance in patients with ulcerative colitis is discussed in another guideline.[13]

When a cancer is found by barium enema or proctosigmoidoscopy, colonoscopy should be done preoperatively to search for synchronous neoplasms. Any polyps detected should be removed by electrocautery if they will not be included in the planned bowel resection. If total colonoscopy is unsuccessful preoperatively because of an obstructing cancer or other technical difficulties, it may be done 3–6 months postoperatively unless unresectable metastases are found at surgery.

Colonoscopy is the preferred method of postpolypectomy follow-up. In addition to being the most sensitive method of polyp detection, it permits the removal of most recurrent polyps. The follow-up interval for patients after removal of a solitary polyp is controversial. It is not known whether they should be reexamined in 1, 2, or 3 years after the initial polypectomy. Since patients with multiple benign polyps appear to be at greater risk than patients with a single polyp, colonoscopy should be repeated in 1 year to search for polyps not seen at the initial examination. In either case, if the first follow-up examination is negative, subsequent follow-up examinations should be repeated approximately every 3 years, as this interval is less than the minimal time in which the polyp-carcinoma sequence occurs in previously grossly normal mucosa.[8]

Patients with adenomatous polyps exhibiting severe dysplasia or carcinoma superficial to the muscularis mucosae can be followed in the same manner as patients with polyps without these features.[8,14] The management of patients with pedunculated adenomas exhibiting carcinoma extending through the muscularis mucosae (invasive carcinoma) is controversial and must be individualized depending upon the operative risk category of the patient. The risk of lymph node spread is less than the risk of colonic surgery in most patients with malignant, pedunculated polyps provided the polyp has been completely resected and adequately processed, and there is no histologic evidence of high-grade carcinoma, vascular or lymphatic invasion, or involvement of the margin of resection.[15,16] Resection of the involved segment of the colon is recommended when these criteria are not met and may also be justified in selected younger, good risk patients. Patients with a sessile polyp in which carcinoma has penetrated the muscularis mucosae should usually undergo surgical resection unless the condition of the patient indicates otherwise.

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Standards of practice of gastrointestinal endoscopy

Guidelines

Physicians and surgeons who practice gastrointestinal endoscopy should meet the following standards. Hospitals should consider these standards in deciding whether to grant or renew privileges in a given gastrointestinal endoscopic procedure.

1. Training

a. Completion of a residency-fellowship training program as outlined in *Guidelines for Training in Gastrointestinal Endoscopy* and expanded in the *Statement on Endoscopic Training.*[1] OR

b. Attendance in a gastrointestinal endoscopic program until training in the endoscopic procedures he or she wishes to perform is equivalent to that outlined in *Guidelines for Training in Gastrointestinal Endoscopy* and expanded in the *Statement on Endoscopic Training.*[1] OR

c. Experience in the endoscopic procedures he or she wishes to perform equivalent to that obtained in a residency-fellowship training program as outlined in *Guidelines for Training in Gastrointestinal Endoscopy* and expanded in the *Statement on Endoscopic Training.*[1] To fulfill this requirement, experience must be documented and skills must be demonstrated.

2. Practice

a. The endoscopist should provide consultation or direct care in medical or surgical aspects of gastrointestinal disease as they relate to the appropriate use of endoscopy and should not be an individual who provides only a technical service. Independent judgment of the indication for and timing of an endoscopic procedure may lead to a decision against performing endoscopy. Sensitivity to cost-benefit considerations is important in making this decision.

b. The endoscopist should also: (1) evaluate the patient's history of reactions to drugs and associated medical conditions; (2) explain the procedure to the patient, including its benefits and risks; and (3) exercise caution in administration of medications and provide for close monitoring of sedated patients.

c. The endoscopic procedure should be performed skillfully and expeditiously, and futile efforts should not be prolonged to the detriment of the patient.

d. A full written report of the procedure and findings should be prepared.

e. Follow-up should be arranged.

3. Privileges

a. The decision for granting of privileges in gastrointestinal endoscopy should be based on the applicant's qualifications with appropriate recognition of individual situations and community practice.

b. This decision can be made by the appropriate Chiefs of Service or by a more broadly-based hospital committee comprised of individuals from various services who have endoscopic training and skills.

4. Continuing education

a. It is imperative that the gastrointestinal endoscopist remain current in this rapidly developing field. Attendance at meetings dealing with endoscopy and active participation in postgraduate programs pertaining to advances in endoscopy are necessary to maintain and improve endoscopic skills.

b. Self-training in new technics occurs in gastrointestinal endoscopy as in other medical and surgical disciplines, but it must take place on a background of basic endoscopic skills as outlined above under **Training** and **Practice**. The endoscopist should have the integrity and insight to determine when additional training is necessary before undertaking a new procedure.

5. Review of performance

a. Performance of the gastrointestinal endoscopist should be reviewed periodically. The numbers of procedures, indications, results, and complications should be made available to the Chief of Service or committee that is responsible for granting privileges. Periodic renewal of privileges is advisable.

b. Endoscopic complications should be discussed at a periodic conference as a mechanism for review of performance and as an educational device.

ASGE Publication No. 1004. Published 1981. Revised March 1986

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The role of endoscopy in the management of esophagitis

Guidelines for clinical application

Reflux acid peptic esophagitis is characterized clinically by retrosternal burning distress (heartburn), which is often accentuated by reclining and relieved by food or antacids. Regurgitation, dysphagia, and odynophagia are also important symptoms. Belching and indigestion are common complaints but are not necessarily related to inflammation of the esophagus. Moderate or even severe esophagitis may be associated with minimal or atypical symptoms.

The patient who develops symptoms of uncomplicated esophagitis or who has mild intermittent dyspepsia or nonspecific chest discomfort should be given an initial trial of therapy without endoscopic evaluation. When there are clinical clues that suggest that reflux may be severe or that other diseases may be present, endoscopy is the diagnostic procedure of choice. Such clues include: (a) initial symptoms of dysphagia or odynophagia[1]; (b) symptoms that are persistent or progressive on therapy; (c) esophageal symptoms in an immunosuppressed patient[2]; (d) the presence of a mass, stricture, or ulcer in a patient with a previous esophagogram; and (e) evidence of gastrointestinal bleeding. Severe reflux esophagitis, infectious esophagitis, and esophageal malignancy need early specific diagnosis for effective therapy. In some patients, an upper GI x-ray series may have revealed a hiatal hernia or gastroesophageal reflux. This radiologic finding alone is not an indication for endoscopy.

Follow-up endoscopy for esophagitis is generally unnecessary and is restricted to the patient whose symptoms fail to respond to therapy, who has an esophageal ulcer, or for whom additional biopsy and cytologic studies are needed to clarify the diagnosis. If surgical management is contemplated, endoscopic evaluation is part of the surgical preoperative workup and may uncover coexistent lesions.

Esophagoscopy is usually performed prior to the initial dilatation of an esophageal stricture to identify any problems that might affect the indications and safety of the dilatation, such as the presence of neoplasm, deep ulceration, or active bleeding. Endoscopy is not routinely done during the course of esophageal dilatation except as necessary for difficult guidewire placement, balloon dilatation, or when a change in the clinical course of the patient requires further clarification. After adequate dilatation of a stricture, repeat endoscopy should be performed to evaluate the area distal to the stricture, if this has not been previously examined. Biopsy and cytology can be obtained if indicated. Routine follow-up endoscopy of patients on long-term dilatation therapy is not necessary unless a change in the clinical course is suspected.

In a patient with severe esophagitis or in one who proves unresponsive to therapy, biopsy may provide useful information. Erythema is an unreliable criterion of esophagitis and does not require routine biopsy. Conversely, abnormal histology may be found by biopsy in patients with reflux symptoms who have normal-appearing esophageal mucosa. Biopsy and cytology specimens may be needed to identify malignancy,[3] monilial or viral esophagitis,[2,4] and metaplastic columnar mucosal change characteristic of Barrett's esophagus.[5] The latter lesion carries a low but definite risk of malignant change. Periodic follow-up endoscopy for Barrett's esophagus may have value, although the optimal frequency of surveillance is uncertain.[6-8]

ASGE Publication No. 1006. Published 1981. Revised March 1986

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The role of colonoscopy in the management of patients with inflammatory bowel disease

Guidelines for clinical application

The purpose of this statement is to provide a current, practical basis for the use of colonoscopy in patients with inflammatory bowel disease (IBD).

Most patients with IBD do not require colonoscopic examination for initial diagnosis. When adequate data are not available from clinical, sigmoidoscopic, or radiologic studies,[1-6] colonoscopy is an important aid in the diagnosis and management of patients with ulcerative colitis and Crohn's disease. When it is clinically necessary to differentiate between ulcerative and Crohn's colitis, colonoscopy with multiple biopsies is helpful.[5] Discrete ulcers, cobblestoning, skip areas, and granuloma formation—all characteristics of Crohn's disease—are among the most useful differential findings.

Colonoscopy is more sensitive than barium enema in determining the anatomic extent of the inflammatory process. When there is strong clinical suspicion of IBD despite negative sigmoidoscopy and barium enema, colonoscopic examination (including biopsies) will determine the presence or absence of colitis. Colonoscopy with multiple biopsies, cytology, or polypectomy is frequently necessary in the evaluation of a polypoid lesion seen on barium enema[5,7]; the radiographic filling defect may represent a pseudopolyp, a true polyp, or a carcinoma. Radiologic study does not permit the determination of the etiology of strictures, particularly in patients with ulcerative colitis. Colonoscopy with multiple biopsies and cytology helps to differentiate benign from malignant strictures. Where recurrent Crohn's disease is questionable after intestinal resection, colonoscopy provides a clear answer.

Patients with universal colitis of more than 7–10 years' duration and patients with left-sided ulcerative colitis of over 15–20 year's duration have an increased risk of developing carcinoma of the colon.[8-10] In view of the recognized limitations and difficulties of clinical and radiologic detection of colon cancer in such patients, periodic colonoscopy with multiple mucosal biopsies from all segments of the colon and rectum contributes to earlier cancer diagnosis.[9,11] In addition, areas of mucosal irregularity and all polypoid lesions of uncertain etiology should be biopsied. Careful pathologic examination of colonoscopic biopsies for dysplatic (precancer)[12-16] changes increases the benefits of periodic colonoscopic evaluation in patients with longstanding colitis. Ideally, surveillance colonoscopy should not be performed during a period of active colitis because of the difficulty in differentiating inflammatory changes from premalignant dysplasia. However, if inflammation is present, biopsies should be obtained from less inflamed or noninflamed areas. The role of colonoscopy with multiple biopsies and cytology in cancer surveillance in patients with Crohn's colitis is not clearly defined.[16,17]

Colonoscopy is hazardous in the presence of severe active colitis, toxic megacolon, suspected perforation, or peritonitis.[5] Preparation for colonoscopy will depend on the clinical status of the patient. In many patients with active inflammatory bowel disease, modification of the usual preparation is necessary. An oral purge with specially balanced electrolyte lavage solutions is preferable to the use of chemical cathartics. In severe disease the sole use of several days of a clear liquid diet may be the safest preparation.

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Statement on endoscopic training

GENERAL CONSIDERATIONS

The rapid development of gastrointestinal endoscopy, its increasing role in clinical diagnosis and management, and its importance in gastrointestinal training programs all indicate the need for a *Statement on Endoscopic Training*. This is intended to expand on the *Guidelines for Training in Endoscopy* published by The Federation of Digestive Diseases Societies (FDDS).

The *objective* of endoscopic training programs is to provide critical, supervised instruction in gastrointestinal endoscopy. Endoscopic procedures are not isolated technical activities, but must be regarded by instructor and trainee as integral aspects of clinical problem solving. Endoscopic decision making and technical proficiency are equally important, and the interdependence of these skills must be emphasized repeatedly during the training period.

The *basic requirements* for successful programs are (1) skilled, experienced, endoscopic supervisors who continually maintain and improve their abilities; (2) trainees with sound general medical or surgical training who have the motivation and aptitude for endoscopy; (3) a structured training experience with ongoing evaluation of each trainee's progress in relation to interests, aptitudes, and career goals, and (4) opportunity for adequate clinical experience. Not all programs need provide training in all endoscopic procedures to each trainee.

IMPORTANT FEATURES OF A TRAINING PROGRAM

A. Training personnel

1. The *endoscopy training supervisor* should be a sound clinician and teacher who is well trained, experienced, and skilled in endoscopy. The supervisor should be responsible for (a) appropriate didactic instruction; (b) supervision of all elective and emergency cases; (c) continuing instruction in endoscopic decision-making, technique, and interpretation of findings; and (d) ongoing evaluation of procedures, reports, and photographic records. The supervisor's judgment will determine when the trainee may progress from directly supervised to less closely supervised and, finally, to independent procedures. Upon completion of training, the supervisor will determine if the trainee is qualified to perform independent gastrointestinal endoscopy.

2. Additional endoscopic instructors should be available when needed to provide general supervision or specific expertise.

3. A gastrointestinal assistant should be available to assist with procedures and to aid in instruction regarding maintenance of endoscopic equipment.

B. Endoscopic training should take place within the framework of clinical care and problem-solving.

1. Endoscopic procedures should be preceded by a careful clinical evaluation, including indications and individual risk factors; most often this should be carried out by the trainee and reviewed by the supervisor.

2. Indications, contraindications, and benefit-risk considerations (including associated medical conditions, history, or drug reactions), should be reviewed with a supervisor before each endoscopy.

3. Sensitivity to cost-benefit considerations and appropriate sequencing of endoscopic and other procedures are important elements in diagnostic and therapeutic decision-making that should be emphasized throughout the period of training.

4. Deciding when not to perform an endoscopy is an important aspect of endoscopic training.

5. The trainee should learn to explain the endoscopic procedure to the patient, including the obtaining of informed consent.

6. The trainee should carry out the immediate post-endoscopy evaluation of the patient, and the program should provide for follow-up evaluation wherever possible.

7. Endoscopic findings should be discussed with the physician-responsible for the patient's care.

C. Technical proficiency must be acquired in a sequential fashion.

1. Trainees should receive instruction in (a) endoscopic anatomy, (b) technical features and capabilities

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of endoscopic equipment, and (c) accessory endoscopic techniques including biopsy, cytology, photography, and electrosurgery.

2. Trainees should observe endoscopic procedures before performing them. Instruction in premedication, preparation of the patient, close monitoring of sedated patients, and the effects of endoscopy on coexisting medical problems is essential at this stage of training.

3. Trainees should perform each type of endoscopic procedure under direct supervision before performing them independently. Obviously, interpretive skills should be developed along with technical expertise. Acknowledging that numbers are relatively imprecise in defining competency, the *Guidelines for Training in Endoscopy* may help supervisors in determining their trainees' progression to independent endoscopy activity.

4. Systematic correlation of endoscopic findings with radiographic and pathologic data (surgical specimens, biopsy, and cytologic material) should be part of each endoscopy.

5. The trainee shall participate in the preparation of complete written reports immediately following each endoscopic procedure.

6. Photographic documentation of lesions should be part of endoscopic procedures and reviewed with the supervisor.

D. An endoscopic facility should be available as described in the *Guidelines for Establishment of Gastrointestinal Endoscopy Areas.*[1]

E. Additional requirements

1. Records should be maintained of all procedures, findings, and complications.

2. Regular conferences should provide for critical discussion of endoscopic cases, complications, and deaths.

3. Teaching collections should be developed including clinical summaries, endoscopic photographs, and relevant radiographic and pathologic material.

4. Records of each trainee's performance should be maintained and reviewed with the trainee periodically. A model training supervisor's evaluation form[2] is available from the ASGE.

F. Endoscopic research strengthens the training experience and should be included in the program.

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Statement on role of short courses in endoscopic training

This statement concerns the role that short courses play in the training of physicians who perform gastrointestinal endoscopic procedures. The statement also deals with certain problems that hospital committees may face in setting guidelines for the granting of privileges to perform gastrointestinal endoscopy by their staff physicians.

For purposes of this statement, **a short course is defined as an organized teaching program lasting less than several weeks, and often only a few days.**

In recent years, issues of what constitutes appropriate endoscopic training, practice, and utilization have been addressed by this Society in great detail. The American Society for Gastrointestinal Endoscopy, through its Standards of Training and Practice Committee and Governing Board, has developed *Standards of Practice of Gastrointestinal Endoscopy*[1] and a *Statement on Endoscopic Training*.[2] These documents have been approved by the Governing Boards of other Digestive Disease organizations and represent a consensus of a broad-based group of gastroenterologists, surgeons, and other specialists. The requirements for training in gastrointestinal endoscopy are described in these publications, and entail either residency-fellowship training or equivalent training from attendance in a gastrointestinal endoscopic program. If experience is acquired outside a formal training program, it must be equivalent to that obtained within such a program. Competence must be documented and skills demonstrated. These principles, which have been accepted by organizations representing both medical and surgical specialties, have been very useful to hospital committees who are responsible for defining criteria for and granting of endoscopic privileges.[3-5]

The rapid development of endoscopic instruments and their widespread distribution to physicians who have not received formal supervised endoscopic training has been associated with a proliferation of short courses on gastrointestinal endoscopy. Such courses usually lack supervised "hands on" training experience with patients; rather they are limited to didactic instruction and the use of artificial models. Attendees of such courses are sometimes granted certificates of attendance, and these, with or without supporting letters, are used by those applying for endoscopic privileges as sufficient evidence of competence to perform endoscopy. Those physicians whose training in gastrointestinal endoscopy has been acquired largely or entirely through courses of this type pose a particularly difficult problem for hospital staff committees concerned with the granting of privileges to perform endoscopy.

Although endoscopic short courses have been utilized as a primary learning modality, it is the consensus of the American Society for Gastrointestinal Endoscopy that these courses, by themselves, do not provide adequate training in endoscopic procedures such as esophagogastroduodenoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography (ERCP), or laparoscopy. Such courses do not allow the attendee to gain experience, interpretive as well as technical, equivalent to that in a residency-fellowship program and do not, therefore, fulfill accepted requirements for training. When trained endoscopists are available in a medical community, there is no rationale for the use of partially trained physicians. The granting of hospital privileges to physicians whose training does not meet established requirements is no longer tenable[4] and may lead to poor patient care. It may also raise potential liability issues for medical staffs and hospital boards.

Short courses do have an appropriate place in endoscopic training. Properly designed, they can serve to augment the trained endoscopist's technical and clinical skills in those studies with which he or she is already experienced. They may also, again in the proper setting, introduce new techniques to the physician who already has a background of basic endoscopic skills and experience. Finally, the introduction of flexible fiberoptic sigmoidoscopy to the nonendoscopist may be facilitated by a short course format, but cannot assure competence in that procedure.

The purpose of previously published guidelines[1,2] and of this statement is to assure that the patient is receiving appropriate, safe, and competent care. In order to provide such assurance, the training and experience of the physician-endoscopist must be documented and his or her skills demonstrated. Privileges granted solely on the basis of training in short courses

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do not assure patients that level of care to which they are entitled in today's medical community.

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Flexible sigmoidoscopy

Guidelines for clinical application

This statement is an assessment of clinical experience with flexible sigmoidoscopy (FS) performed primarily with a 60-cm instrument and contains observations on cost containment.[1]

Rigid sigmoidoscopy (RS) is of value in screening asymptomatic average risk adults over age 40–50 for prevention and early detection of rectosigmoid cancer, and the cost-benefit relationship appears favorable.[2] However, screening RS has not been widely practiced. Comparative studies indicate that FS detects an average of three times as many polyps and cancers and is a more acceptable procedure to patients than RS.[1, 3-8] Recent studies also demonstrate the safety and efficacy of FS performed by properly trained individuals.[9-11] FS is more expensive than RS in original equipment cost and maintenance, as well as in time spent for preparation, performance, and cleaning. In spite of its greater cost, the higher diagnostic yield of both polyps and cancer and more favorable patient acceptance with FS indicates that FS should replace RS in screening for colonic neoplasms.

The indications for FS other than screening appear to overlap those of RS except that its greater length makes the flexible sigmoidoscope more useful in assessment of roentgenographic findings in the sigmoid colon. Either FS or RS is appropriate prior to barium enema in the initial evaluation of colonic symptoms. RS may be preferable to FS in clinical situations when specimens for culture or large mucosal biopsies are required and for routine follow-up examinations of patients with inflammatory diseases of the rectum or distal sigmoid colon. Neither FS nor RS is a substitute for total colonoscopy when appropriate indications for colonoscopy exist. Small sessile polyps (<0.5 cm) found by FS may be either hyperplastic or neoplastic and should be biopsied. The finding of a neoplastic polyp during sigmoidoscopy is an indication for total colonoscopy to search for additional polyps or cancer.[12,14] FS should not be used for polypectomy unless the entire colon is adequately prepared to minimize the risk of electrocautery-induced explosion. Contraindications to flexible sigmoidoscopy depend on the importance of potential information to be gained. Relative contraindications include fulminant colitis, severe acute diverticulitis, toxic megacolon, acute peritonitis, a poorly prepared colon, and an uncooperative patient.[1]

What constitutes proper training for FS is controversial, but both medical and surgical endoscopy societies agree that training is necessary. Documented competence in FS should precede the granting of hospital privileges. Two or 3-day courses cannot assure competence but may be useful for the introduction of a nonendoscopist to FS. A shorter 35-cm flexible sigmoidoscope was introduced for use by the nonendoscopist and permits quicker and better tolerated examinations with very reasonable diagnostic yields.[1, 15-17] Both 60-cm and 35-cm FS are apparently safe and effective when used by the nonendoscopist after an appropriate number of supervised patient examinations. Twenty to 30 supervised procedures is the minimum number required to attain competency with the 60-cm instrument compared with 7–10 procedures for the 35-cm sigmoidoscope.[1]

In summary, FS (60-cm or 35-cm) is two to three times more effective than RS for detecting neoplasms of the lower colon and rectum.[1] Cost-effectiveness comparisons between the two procedures have not been made. A favorable cost comparison for FS depends upon moderation in setting fees. The professional fee component of the total charge for FS should not greatly exceed the usual fee for RS and should bear no relation to the fee for colonoscopy. The coding designation for flexible sigmoidoscopy should be clearly differentiated from the codes for colonoscopy.

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The role of endoscopy in the surveillance of premalignant conditions of the upper gastrointestinal tract

Guidelines for clinical application

During the last two decades, there has been a growing awareness that cancer of the esophagus and stomach may develop in association with several underlying diseases or following previous surgery for benign disease. The literature has been difficult to evaluate in terms of formulating surveillance guidelines since most published studies are retrospective and deal with small numbers. This statement is an attempt to establish guidelines, keeping in mind cost considerations, with respect to the following conditions: achalasia, columnar epithelium-lined esophagus (Barrett's esophagus), pernicious anemia, gastric polyps, and postgastric surgery for benign disease. Well designed long-term, population-based prospective studies which more accurately define risk for malignancy are needed.

Guidelines for the appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance from these recommendations.

ACHALASIA

Esophageal cancer develops in 1.7%–8.2% of patients with untreated achalasia. These cancers appear late with detection rarely occurring before 15 years of symptomatic disease.[1-4]

The risk of developing esophageal cancer after treatment for achalasia with effective balloon dilatation or esophagomyotomy early in the course of disease is only minimally higher than the risk of esophageal cancer in the general population.[5]

Recommendations

1. If effective dilatation or myotomy has been performed early in the course of disease, there is no need for endoscopic surveillance.

2. For the rare untreated patient, periodic endoscopic surveillance after 15 years of symptoms is justified.

3. Patients who are treated later in the course of disease possibly may be at increased risk for malignancy, and the role of endoscopic surveillance has not been determined.

COLUMNAR EPITHELIUM-LINED ESOPHAGUS (BARRETT'S ESOPHAGUS)

There is a well recognized risk of developing adenocarcinoma in the esophagus of patients with Barrett's esophagus. Retrospective reviews have reported this risk to be 8%–10% but these figures may be high because of selection bias.[1-3] The cancer may be microinvasive and multifocal.[4,5] Most authors agree that an adequately performed antireflux operation, while healing inflammation, ulceration, and/or strictures, does not reverse the malignant potential of the esophagus. A recent study challenges this position but needs confirmation.[6]

Recommendation

Although the long-term benefits of endoscopic surveillance have not been determined,[7] it is our consensus that all patients with histologic confirmation of Barrett's esophagus might benefit from periodic endoscopic examination with multiple brushings and biopsies of the columnar portion of the esophagus.

GASTRIC POLYPS

Gastric mucosal polyps are rare, and only the adenomatous types carry a risk for malignancy. Size, distribution, or number of polyps do not adequately differentiate adenomatous from non-neoplastic polyps; both may be associated with atrophic gastritis.[1,2] Most polyps are incidental findings and, although studies are few, do not seem to change in size over time.[3] Adenomatous polyps have a well-defined risk of cancer with a size-dependent relationship.[1,2,4-6] En-

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doscopic biopsies may miss areas of focal cancer in adenomatous polyps.[7]

Recommendations

1. All patients with polypoid defects of any size detected radiographically should be initially endoscoped with biopsy and/or removal of the lesions.

2. Polyps causing symptoms, such as obstruction and bleeding, should be removed, preferably endoscopically.

3. Asymptomatic pedunculated polyps should be removed endoscopically when feasible. For those lesions which cannot be removed endoscopically, surgical excision may be considered.

4. Asymptomatic, sessile polyps should be initially biopsied or excised. Subsequent treatment will depend on the histology, size, and number of the polyps present: (a) If non-neoplastic, no surveillance is indicated. (b) If adenomatous and less than 2 cm and solitary or few, the polyp(s) should be endoscopically excised if feasible and the patient followed with periodic endoscopy. If adenomatous and less than 2 cm and multiple, the polyps should be endoscopically excised where feasible and the patient followed with endoscopy; if the polyps cannot be removed endoscopically, surgical excision should be considered. If adenomatous and greater than 2 cm, the polyp should be removed either by endoscopic polypectomy or operative resection.

PERNICIOUS ANEMIA

Whether pernicious anemia alone, or pernicious anemia associated with atrophic gastritis is a precursor to gastric cancer is unknown.[1-5] One population study suggests that the incidence of gastric cancer in patients with pernicious anemia is only slightly increased over that in the general population and does not justify the cost of periodic surveillance.[6]

Recommendation

Routine endoscopic surveillance is not indicated in patients with pernicious anemia.

POSTGASTRIC SURGERY

Cancer occurring in patients previously operated on for benign gastric or duodenal ulcer has been recognized for several decades in autopsy and retrospective studies. In some series, the incidence ranges from 2%–8.7%.[1-3] Other series have demonstrated no increased risk.[4,5] A recent large population-based study suggests the risk of gastric cancer in patients operated on previously for benign peptic ulcer disease is no greater than the risk of developing a spontaneous gastric cancer in the same population.[6]

Recommendation

In the asymptomatic patient, annual or periodic endoscopic surveillance is not indicated.

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The role of endoscopy in the management of the patient with peptic ulcer disease

Guidelines for clinical application

This statement defines the role of upper endoscopy in the diagnosis and management of patients with known or suspected peptic ulcer disease. Most patients with dyspepsia as an isolated symptom (epigastric pain without weight loss, evidence of bleeding, obstruction, perforation, or associated multisystem disease) may be treated empirically for 6–8 weeks by withdrawing offending agents (alcohol, ulcerogenic medication, and cigarettes) and prescribing anti-ulcer agents.[1]

Those patients who have no response to therapy after 7–10 days, those who remain symptomatic after 6–8 weeks of therapy, those with symptom recurrence, those who show signs of a severe systemic illness, and those who develop complications of peptic disease should undergo esophagogastroduodenoscopy as the initial diagnostic evaluation.[1] The upper gastrointestinal barium x-ray series, although it is usually less expensive than upper gastrointestinal endoscopy, is hampered by a comparatively high rate of diagnostic inaccuracy and does not allow for biopsy and cytologic evaluation.[2]

Patients with a prior upper gastrointestinal x-ray demonstrating a radiologically "malignant" or "indeterminant" gastric ulcer should always undergo endoscopy and biopsy unless the additional information will not influence the patient's management. An upper gastrointestinal x-ray suggesting a "benign" gastric ulcer should be followed in most cases by endoscopic evaluation to obtain a tissue diagnosis. When a gastric ulcer is demonstrated as clearly benign on a double-contrast barium study, it may not be necessary to obtain immediate endoscopic confirmation, but the ulcer should be followed to complete healing.[3] Some individuals, such as the young patient with a small prepyloric ulcer taking ulcerogenic drugs, may not need endoscopic examination.[4] Biopsy adds to the accuracy of endoscopic examination of gastric ulcer,[5,6] and multiple biopsies should be obtained[7] except when the ulcer is actively bleeding. The addition of cytology to biopsy will increase the diagnostic yield.[8] Some radiographically benign-appearing gastric ulcers have been found to be malignant after multiple endoscopic biopsies are obtained.[5,6,9-11] Follow-up endoscopy or double-contrast barium x-ray should be obtained in 8–12 weeks in the majority of cases to document complete healing. Repeat endoscopy may also be indicated if symptoms persist or if the initial endoscopic appearance and/or histology were not clearly benign, or biopsy was not initially obtained because of bleeding.

If a previous upper gastrointestinal x-ray shows a discrete crater in the duodenum as the only lesion, endoscopy is not usually indicated. However, if the clinical response to proper medical therapy is not prompt and sustained, endoscopy can help establish or exclude other possible conditions including gastric ulcer, neoplasms, or esophagitis. If the x-ray findings are normal or equivocal (mild deformity, spasm, irritability, or thickened folds), endoscopy can establish a precise diagnosis. In the absence of typical clinical symptoms and response to medical therapy, a patient should not be diagnosed as having duodenal ulcer unless at some time an ulcer crater has been clearly documented by x-ray or endoscopy. It should be kept in mind that although occasionally both duodenoscopy and x-ray may be necessary to diagnose duodenal ulcer disease,[13] duodenoscopy is considerably more accurate than x-ray in determining the presence and characteristics of duodenal ulcer.[14-20] Biopsy of a duodenal ulcer is not indicated and endoscopy has no role in the usual follow-up of uncomplicated duodenal ulcer.

Endoscopy is useful in evaluating and managing some of the complications of peptic ulcer disease:

Bleeding. In patients with active upper gastrointestinal bleeding including those with a history of peptic ulcer disease, upper gastrointestinal endoscopy is the most useful initial diagnostic procedure.[12] The examination can be performed promptly following stabilization of vital signs to determine the cause or location of the bleeding source. Previous studies have shown that patients with known gastric or duodenal ulcer often bleed from other lesions.[13] Control of bleeding may be accomplished using endoscopic coagulation devices.

Obstruction. Gastric outlet obstruction is often due to peptic ulcer disease, which may cause either acute gastric retention from inflammation and edema or

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chronic retention from associated cicatricial stenosis of the intestinal lumen. When obstruction occurs, endoscopy may help to exclude other lesions which may cause gastric retention. Endoscopic guided balloon dilatation may alleviate a partial obstruction.

Endoscopy may be indicated prior to surgical therapy of peptic ulcer disease to look for the possible coexistence of other lesions that may alter the surgical plan (such as other ulcers, neoplasm, or esophagitis) or to demonstrate that an active ulcer crater is indeed present.

Endoscopy is contraindicated when a perforated ulcer is suspected.

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The role of endoscopy in the patient with lower gastrointestinal bleeding

Guidelines for clinical application

Endoscopy is valuable in the diagnosis of the cause of lower gastrointestinal bleeding, and it offers the opportunity for treatment of selected patients with this problem. Endoscopic procedures must be integrated with other studies to reach a correct diagnosis rapidly, safely, and economically. In all patient, evaluation begins with a history and physical examination. The sequence of other tests depends on many factors, especially the rate of bleeding.

CHRONIC BLEEDING

Chronic lower gastrointestinal bleeding is the passage of blood per rectum over a period of several days or longer, and usually implies an intermittent or slow loss of blood. The patient with chronic bleeding can have occult fecal blood, occasional episodes of black or maroon stools, or small quantities of visible blood per rectum.

Occult fecal blood

Neoplasia of the gastrointestinal tract, especially the large bowel, is the most important concern in a patient over the age of 40 with occult fecal blood. Digital rectal examination and anoscopy are advisable because occult bleeding may arise from an anal or distal rectal lesion. Much more often, however, the source of blood is more proximal, so examination of the entire rectum and colon must be carried out.

The rectum and sigmoid may be examined by a rigid or flexible sigmoidoscopy. Flexible sigmoidoscopy allows evaluation of two to three times more large bowel and discovers two to 10 times more lesions than a rigid instrument. The more proximal colon must be evaluated by colonoscopy or double contrast barium x-rays. If x-rays are obtained and they do not reveal a potential bleeding site, colonoscopy should be performed, since a carcinoma, polyp, inflammatory lesion, or other source of blood loss is identified in 20%–40% of such patients.[1-6] If barium x-rays do demonstrate a lesion, colonoscopy usually is necessary to confirm its presence and nature and, in some cases, to treat a lesion. The therapeutic potential of colonoscopy, including polypectomy and control of bleeding sites by electrocoagulation or photocoagulation, is an additional important factor in favor of colonoscopy over flexible sigmoidoscopy and contrast enema x-rays in the initial evaluation of patients with occult rectal bleeding.[7-11] Conversely, if colonoscopy cannot be completed to the cecum or is suboptimal, air-contrast barium enema should be obtained before investigating the upper gastrointestinal tract. Upper endoscopy to check for an upper gastrointestinal source of bleeding should be considered if a colonic source is not found, particularly in a patient who is symptomatic or anemic.[12] The occasional patient with clinically significant chronic bleeding from the small intestine may be diagnosed by barium x-rays, preferably with enteroclysis, angiography, nuclear medicine scans, small bowel endoscopy, or intraoperative maneuvers including operative endoscopy.

Intermittent melena

The diagnostic evaluation of a patient with intermittent melena should begin with upper endoscopy since an upper tract lesion is most likely in this setting. Lower tract evaluation and small bowel studies similar to that described for occult bleeding are indicated if no upper source is found.[5]

Scant hematochezia

Chronic intermittent passage of small amounts of visible red blood is the most common pattern of lower gastrointestinal bleeding. The majority of such patients are bleeding from an anal lesion, and most of the others bleed from lesions in the rectum or distal colon. Historical features are often helpful in differentiating among possible diagnoses. For example, spots or drops of blood after defecation suggest an anal lesion, and streaks of blood on formed stools point to a rectal or distal colonic origin.

The diagnostic evaluation of patients with scant hematochezia includes careful inspection of the anus, digital rectal examination, anoscopy, and sigmoidoscopy. The diagnostic yield is higher when evaluation is performed during a bleeding episode. If flexible sigmoidoscopy is performed, the instrument should be

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retroflexed in the rectum to view the anorectal junction from above, unless an adequate examination with an anoscope has been done. Stool at the highest extent of examination by sigmoidoscopy may be sampled for occult blood and, if negative, supports a clinical impression of anorectal bleeding.

The entire colon should be evaluated by colonoscopy or air-contrast barium enema if a convincing source of blood is not found in the anorectum or sigmoid. The decision to obtain one of these studies is based on the patient's age and general condition and the presence of risk factors for neoplasia. For example, young patients with scant hematochezia and an obvious anal bleeding site are not usually subjected to colonoscopy or x-ray, whereas middle-aged and older individuals may need further examination even in the presence of an anal lesion. If colonoscopy or x-rays are not obtained initially, persistent or recurrent bleeding should prompt more thorough evaluation.

ACUTE BLEEDING

Acute lower gastrointestinal bleeding is arbitrarily defined as bleeding of less than 3 days' duration. There is overlap with the chronic bleeding category, and some patients with acute bleeding actually fit better in the chronic bleeding category because the rate of bleeding is very slow and the volume of blood loss is scant. For the purpose of this discussion, acute bleeding is subdivided by amount lost into either moderate bleeding or massive bleeding.

Moderate bleeding

Acute loss of blood per rectum, not sufficient to require immediate transfusion, can be termed moderate. Moderate blood loss comprises the majority of acute bleeding instances and is characterized by either the spontaneous cessation of rapid bleeding after a brief period, or by rectal bleeding of slower rate but longer duration. Moderate bleeding infrequently leads to significant hemodynamic changes in the affected individual, and one may therefore proceed immediately with diagnostic tests. Early in the evaluation of acute bleeding, upper or lower gastrointestinal barium contrast studies are not advised because they will interfere with subsequent endoscopic or angiographic studies which might have been diagnostic if done beforehand.

The anus and rectum may be the source of moderate blood loss, and must be examined carefully by either a rigid or flexible endoscope in the same manner as in the case of chronic blood loss discussed above. More often the ano-rectum will not be the site of bleeding, and colonoscopy should be performed next. Initial colonoscopic examination of the unprepared bowel is difficult and frequently unsuccessful, but will occasionally demonstrate an area of sharp demarcation between feces free of gross blood proximally and liquid or clotted blood distally. Colonoscopy will more likely identify a bleeding site if the patient is first rapidly prepared with oral lavage. If bleeding has stopped and the patient does not require emergency surgery, or if an unprepared examination has not been done, then a complete colonoscopic examination of a well-prepared colon should be done. If complete colonoscopy is negative, and if bleeding does not recur within a few days, barium x-rays may be considered. The alternatives are to carefully monitor the patient, to obtain other imaging studies detailed below or to repeat colonoscopic examination if bleeding recurs.

Massive bleeding

A small number of patients have acute loss of large volumes of blood per rectum from a source in the upper or lower gastrointestinal tract. The first priority is to stabilize the patient with intravenous fluids and transfusions if necessary. The diagnostic work-up begins while these resuscitative efforts are underway or as soon as the patient is stable, depending on the urgency of the situation.

A nasogastric tube should be inserted and the gastric aspirate observed for visible blood. If there is suspicion of an upper gastrointestinal bleeding source, upper endoscopy should be performed even if the stomach contains no blood. Barium contrast studies are not indicated at this time.

The distal large bowel is investigated with anoscopy and sigmoidoscopy. Preparation with enemas may or may not be practical, depending on the rate of bleeding. If no bleeding site is seen in the rectum or rectosigmoid, the entire colon should be examined. There are two strategies for evaluation of the colon in these patients: (1) angiography, with or without a preceding radionuclide scan (sulfur colloid or technetium-pertechnetate labeled red cells); and (2) colonoscopy.[13]

Angiography has the advantages of (1) localization of a rapidly bleeding site, and (2) potential for treatment of the hemorrhage by infusion of embolization. Many angiographers prefer that a nuclear medicine scan be obtained first. If the scan is negative, the likelihood of demonstrating a bleeding point angiographically is lower than if a scan is positive and would favor proceeding to colonoscopy. Disadvantages of angiography include the requirement for available and skilled imaging experts on short notice; risks of contrast media allergic reactions or nephrotoxicity as a consequence of prolonged or repeated studies; other complications of an invasive procedure, e.g., vascular thrombosis; and the possibility of unsuccessful diagnosis or treatment because of anatomic or other technical problems.

The alternative strategy of emergency colonoscopy has these advantages: (1) it discloses a bleeding lesion of the colon in 50%–70% of patients examined[14-16]; (2) definitive treatment of an identified lesion by snare cautery, fulguration with electrocautery or heater probe, or laser photocoagulation is often possible during the emergent or a subsequent elective colonoscopic procedure; and (3) massively bleeding lesions that have stopped will more often be identifiable by colonoscopy than by angiography. Disadvantages of colonoscopy include the need for available and skilled endoscopists, an increased risk of perforation when colonoscopy is performed in an ill patient with blood in the colon, the delay of 1–3 hours required to prepare the colon, and the possibility of unsuccessful diagnosis or treatment because of technical problems. The colon is cleansed by conventional enemas or preferably by lavage with 3–4 liters of electrolyte solution given orally or through a nasogastric tube. The delay required for preparation is rarely a significant disadvantage since other necessary resuscitative measures may be carried out at the same time, and only rare patients bleed so rapidly that a delay of a few hours jeopardizes hemodynamic stability.

The decision for initial evaluation by either angiography, nuclear scans, or colonoscopy is a clinical one and does not preclude subsequent examination by the alternative techniques. Comparative long-term morbidity and mortality data from use of these modalities are not yet available.

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Informed consent for gastrointestinal endoscopy

Over the last 30 years informed consent has undergone a transformation from an ethical concept to a legal doctrine. It is based on the ethical principles of self-determination and autonomy.[1] Courts recently have begun to find physician liability based on the failure to obtain adequate informed consent.[2-4] All 50 states have adopted the legal notion of informed consent. The duty of all gastrointestinal endoscopists is to obtain legally adequate informed consent before performing any endoscopic procedure on a patient. Although there is no one absolute prescribed way to obtain adequate informed consent, the purposes of this guideline are to introduce the Doctrine of Informed Consent to endoscopists and to present a reasonable and effective method of obtaining it.

The crux of the Doctrine of Informed Consent is disclosure. The disclosure requirements as defined legally are of two types. One or the other is applied in each state and it is recommended that each endoscopist learn the applicable standard in his or her state.[5] The first is the majority or professional disclosure standard.[6] Most jurisdictions apply this standard of disclosure. It requires that the gastrointestinal endoscopist disclose to the patient that amount of information that a physician in good standing would provide. The second disclosure standard is the minority or lay standard.[7] Under this standard, the endoscopist must provide information which a reasonable lay person would consider material and significant in consenting to a proposed procedure.

The elements of adequate disclosure are the same under either standard. These include the following: (1) the nature of the proposed procedure; (2) the underlying reason why the procedure is necessary and its goals; (3) the risks and complications of the procedure, including their relative incidence; and (4) reasonable alternatives to the proposed procedure.

The endoscopist should be certain to explain the procedure to the patient including what will occur before, during, and after the procedure. The patient should be told why the procedure is necessary, and the anticipated benefits should be outlined. The risks and possible complications of the procedure must be described. Not every possible risk or complication need be disclosed,[6] but those which occur with significant frequency and those of a serious nature should be presented. If drugs are to be used, the endoscopist should include their hazards and risks. It is equally important to present the possible alternatives to the procedure, including ones that may be more hazardous.[4] If no alternatives exist, the patient should be so informed.

The endoscopist is best advised to obtain the patient's informed consent personally.[8] This duty is not generally a delegatable one, although interstate and interhospital policies may vary. The use of preprinted materials, diagrams, and other audiovisual materials can be useful adjuncts to the patient's decision-making, but are not substitutes for the physician-patient interaction. The patient should be given adequate time to deliberate, and the endoscopist should solicit and answer questions.[8]

Most hospitals require a formal writing such as a consent form to satisfy their informed consent policies, although this writing is required by law in only a few states. *The endoscopist must be mindful of the fact that informed consent is a process of disclosure and deliberation, not merely the signing of a form.* The typical generic consent form serves little useful purpose other than to evidence that the patient signed it. There may be a role for specific consent forms for each procedure, written in simple lay language.[9-11] Specific forms could include the particular and specific data for the procedure for which it is designed.

The endoscopist should be certain to document that he or she obtained the patient's informed consent prior to the performance of a procedure. An appropriate note should be entered into the patient's hospital or office record. It is also advisable that the endoscopist have a third party witness the informed consent interview.[9] This witness may prove invaluable in the event that any questions arise concerning the validity or extent of disclosure. Although tape recording and videotaping of informed consent interviews may be useful in certain dangerous procedures or with high risk patients, they are not generally recommended.[9,12]

There are four recognized exceptions to the legal Doctrine of Informed Consent. When any of these are

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applicable to a clinical situation, the endoscopist's duty to obtain the patient's informed consent does not apply. They are as follows: (1) the emergency exception, (2) incompetency, (3) therapeutic privilege, and (4) waiver.

When there is inadequate time due to clinical exigency and there is a threat to a patient's life, an endoscopist may forego obtaining the patient's informed consent. Before invoking this exception, be certain that the emergency is one which truly is life threatening[12] or is necessary to relieve pain and suffering.[14]

An incompetent patient cannot sufficiently participate in the informed consent process. Nonetheless, the endoscopist treating an incompetent, regardless of whether the patient is incompetent by virtue of age, alcohol, or drugs or by intellectual impairment, still has a duty to obtain the informed consent of that patient's legal guardian. In reality, incompetency is no exception at all and is best viewed that way for clinical purposes.

There are a small number of patients who will be harmed by the disclosure necessary to obtain informed consent. Although the degree of harm necessary to trigger this exception, therapeutic privilege, is unclear, an endoscopist may invoke it in selected clinical situations. It must be kept in mind that therapeutic privilege is probably overutilized by physicians. They overestimate the extent to which patients will find disclosure disagreeable.[1] Indeed, studies indicate that patients do not decline procedures and therapy because of negative disclosure and that generally they appreciate and want this information.[1,15–17]

Finally, a patient may elect not to be told the elements of disclosure herein described. In this case, the endoscopist's duty to obtain informed consent is nonapplicable. When the waiver exception is relied upon, the endoscopist should be certain that the patient has full knowledge and understanding of his or her right to informed consent and that he or she voluntarily relinquishes it.[18] As with the application of any of the exceptions, appropriate documentation is essential.

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Methods of granting hospital privileges to perform gastrointestinal endoscopy

PRINCIPLES OF CREDENTIALING

A. Purpose

The purpose of this statement is to outline principles and provide practical suggestions to assist hospital credentialing committees in their task of granting privileges to perform gastrointestinal endoscopy. In conjunction with the standard JCAHO guidelines for granting hospital privileges, implementation of these methods should help hospital staffs insure that endoscopy is performed only by individuals with appropriate competency, thus assuring high quality patient care and proper procedure utilization.

B. Statement of the problem

The general principles of defining competency in gastrointestinal endoscopy are provided by the ASGE guidelines on *The Standards of Practice of Gastrointestinal Endoscopy* and the *Statement on Endoscopic Training*. Although hospitals have frequently used these guidelines in their independent development of credentialing standards, many have requested more specific or practical suggestions how these principles might be best implemented.

C. Uniformity of standards

Uniform standards should be developed which apply equally to all hospital staff requesting privileges to perform endoscopy, and to all areas where endoscopy is performed within a given institution. Criteria must be established which are medically sound, not unreasonably stringent, and which are applicable in common to all those wishing to obtain privileges in each specific endoscopic procedure. The goals must be quality assurance, patient protection, and cost containment, not arbitrary restraint of practice.

D. Specificity of credentialing

Privileges should be granted for each major category of endoscopy separately. The ability to perform one endoscopic procedure does not imply adequate competency to perform another. Associated skills generally considered to be an integral part of an endoscopic category may be required before privileges for that category are granted. For example, competency in polypectomy and electrocoagulation must be documented before colonoscopy privileges can be granted. The application for privileges will require adequate verification of competency for each separate procedure.

E. Responsibility for credentialing

Determination of who does credentialing and which specific methods are chosen to perform the process remains always the individual responsibility of each hospital. When defining privilege granting criteria and procedures, it should be kept in mind that hospital trustees and *all* medical staff share common responsibility and liability for *all* procedures performed within their institution. It is highly desirable to establish a *multidisciplinary endoscopic procedure committee* to advise the credentialing body regarding initial granting of privileges, to monitor ongoing procedure performance and outcome, and to assist in the renewal of privileges. Every attempt should be made to cooperate between hospitals with overlapping staff to reduce the time and paperwork in the credential granting process.

F. Competency in the diagnosis and management of gastrointestinal disorders

The decision of who should perform gastrointestinal endoscopy in a given hospital should be based on the applicant's knowledge, training and experience in the overall management of gastrointestinal disease, as well as competency to perform the endoscopic procedure. Flexible sigmoidoscopy is generally considered a separate category. With adequate supervised training it may be performed by physicians without other endoscopic skills or specialized training in gastroenterology or surgery (see ASGE guidelines, *Flexible Sigmoidoscopy*).

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II. DEFINITION AND DOCUMENTATION OF COMPETENCY

A. Formal fellowship or residency training in gastroenterology or surgery

1. Duration of training: Training should be of adequate duration to provide familiarity with the patients and diseases requiring endoscopic evaluation. There must be an understanding of the indications, complications, and expected advantages of diagnostic and therapeutic endoscopy, as well as cost considerations, and comparisons with alternative approaches.

2. Endoscopic experience: The total time spent during training, learning and performing endoscopic procedures must be adequate for each major category for which privileges are requested. The number of cases which must be observed, performed under supervision, and performed independently necessary to obtain competency varies tremendously. The following numbers of cases performed personally by each trainee during training should serve as a guideline for minimal required endoscopic experience: esophagogastroduodenoscopy, 50–75; colonoscopy, 50; polypectomy, 15; and ERCP, 35–50.

3. Certification: The applicant's endoscopic training directors should confirm in writing the training, experience (including the number of cases for each procedure for which privileges are requested), and actually observed level of competency.

B. Training and experience outside of a formal fellowship or residency program

Equivalent training, obtained outside of a formal program, must be equal to that described above. Certification of experience by a skilled endoscopic practitioner must include a detailed description of the nature of "informal" training, the number of procedures performed with and without supervision, and the actual observed competency of the applicant for each endoscopic procedure for which privileges are requested. It is generally no longer acceptable for physicians to acquire equivalent endoscopic experience by performing unsupervised procedures when skilled endoscopists are available in the medical community. Likewise, attendance at short endoscopy courses which do not provide supervised hands-on training experience with patients is not an acceptable substitute in the development of equivalent competency (see ASGE guidelines, *Statement on Role of Short Courses in Endoscopic Training*).

C. New procedures

As endoscopy evolves, new procedures develop for which privileges may be requested. The process for credentialing depends on the background skills and privileges of the applicant and whether the new procedure is a minor or major variant of established techniques. For minor extensions of demonstrated skills, reading or viewing video tapes may be sufficient training. Some new procedures may require formal training or "hands-on" equivalent supervised experience with adequate written documentation. Endoscopic sphincterotomy is an example of an extremely complex and high risk procedure requiring extensive training and experience. Therefore, privilege granting for endoscopic sphincterotomy requires documented competency.

D. Proctoring

Recognizing the limitations of written reports, proctoring of applicants for privileges in gastrointestinal endoscopy by a qualified, unbiased staff endoscopist may be desirable, especially when competency for a given procedure cannot be adequately verified by submitted written material. Proctors are chosen from existing endoscopy staff or are solicited from regional endoscopic societies. Criteria of competency for each procedure should be established in advance. It is essential that proctoring be carried out in an unbiased, confidential, objective manner. The procedural details of proctoring should be provided to the applicant and to the credentialing body of the hospital. A satisfactory mechanism for appeal must be established for individuals for whom privileges are denied or are granted in a temporary or provisional manner.

E. Monitoring of endoscopic performance

To assist the hospital credentialing body in the ongoing renewal of privileges, a mechanism should be developed to monitor each staff endoscopist's procedural performance. A *multidisciplinary endoscopy committee*, as described above, could be charged with monitoring endoscopic utilization, diagnostic and therapeutic benefits to patients, complications, and tissue review. A minimum number of cases performed each year for each major endoscopic category may be required to renew privileges. These functions should be accomplished using established peer review methodology and available endoscopic audit criteria. The committee should review in an unbiased random sample the appropriateness of the indications for endoscopy, the impact on management of the patients' problems, the nature and adequacy of safety precautions, and the incidence and cause of all complications. Guidelines for the utilization of endoscopy prepared by the American Society for Gastrointestinal Endoscopy and other societies are available to assist in the periodic reassessment of endoscopic privileges.

F. Continuing education

Continuing medical education related to endoscopy should be required as part of the periodic renewal of endoscopic privileges. Attendance at appropriate local or national meetings and courses is encouraged.

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The role of laparoscopy in the diagnosis and management of gastrointestinal disease

Guidelines for clinical application

Laparoscopy (peritoneoscopy) is a procedure which allows direct examination of large portions of the surface area of the liver, gallbladder, spleen, peritoneum, and pelvic organs.[1,2] The addition of directed biopsy increases diagnostic accuracy. Laparoscopy is simple, safe, and well-tolerated under local anesthesia. General anesthesia is neither necessary nor desirable, except in special circumstances. While sterile conditions are required, laparoscopy need not be performed in an operating room; routine backup by a surgical or anesthesia team is usually not required. The procedure may be performed on an outpatient basis, although more commonly it is an inpatient procedure. Despite the advent of newer imaging techniques (e.g., computerized tomography, ultrasonography, magnetic resonance imaging), with fine needle biopsy capability, laparoscopy remains a valuable tool when appropriately applied in a thoughtful diagnostic plan. In the final analysis, local experience and results will determine the preference for each of these diagnostic modalities.[3,4]

INDICATIONS

Laparoscopy may be useful in the evaluation of suspected hepatic malignancy either primary or metastatic.[5,6] Eighty to 90% of these lesions are present on the hepatic surface and up to two thirds of the liver's surface may be inspected. Blind percutaneous liver biopsy or image-guided needle aspirate biopsy is frequently employed as the initial diagnostic modality for suspected hepatic malignancy. Laparoscopy is appropriate when hepatic tumor is suspected but not proven by percutaneous biopsy techniques. Laparoscopy is also useful in detecting small (less than 2 cm) neoplasms not seen by imaging modalities. When laparoscopy is utilized in the diagnosis and staging of lymphoma[7] and pancreatic[8] or esophageal cancer,[9] exploratory laparotomy may be averted in a significant percentage of cases.[10]

Blind percutaneous liver biopsy is often used to confirm the diagnosis of cirrhosis. When this approach yields inconclusive results, laparoscopy should be considered.[11] Since percutaneous liver biopsy may be more difficult and hazardous in patients with small livers or in those with large volume ascites, laparoscopy is preferable to blind biopsy. While it is believed that laparoscopic guided liver biopsy is safer in cirrhotic patients with borderline coagulation defects, this point has not been verified.

While the determination of the etiology of ascites is usually straightforward by history, physical exam, and analysis of ascitic fluid, the diagnosis of tuberculous or carcinomatous ascites may be elusive. In such cases, laparoscopy with biopsy is highly accurate.[12]

In rare instances, laparoscopy may be useful in the emergency evaluation of abdominal trauma or other acute situations as well as the investigation of abdominal pain. The diagnostic yield in the latter condition is low. When laparoscopy is done for acute conditions, anesthesia and surgical standby should be arranged. In the diagnosis of obstructive jaundice, laparoscopy has been supplanted by cholangiography.

COMPLICATIONS

The complications of laparoscopy may be categorized according to the various phases of the procedure. Problems related to induction of the pneumoperitoneum and insertion of the laparoscope include cardiac arrhythmias, perforation of a hollow viscus, puncture of a solid organ, bleeding, and subcutaneous emphysema. Laparoscopic liver biopsy may be complicated by bleeding and/or bile peritonitis. These may also occur as a consequence of blind percutaneous liver biopsy. In most reported series, complications are

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minor and occur with a frequency of 1%-5%, and the mortality rate is approximately 0.05%.[13,14]

CONTRAINDICATIONS

Contraindications for laparoscopy are relative and include the uncooperative patient, uncorrectable coagulation defects, severe congestive heart failure, respiratory insufficiency, suspected acute, diffuse peritonitis, and the presence of distended bowel. If tense ascites is present, large volume paracentesis can be performed as the preliminary step in the laparoscopy. Previous laparotomy incision(s) may necessitate alteration of the usual trocar insertion site or may represent a contraindication to the procedure.

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Preparation of patients for gastrointestinal endoscopy

Guidelines for clinical application

This statement summarizes current methods of preparing patients for gastrointestinal endoscopy. The goal of preparation for all endoscopic procedures should be to make possible a safe, comfortable, accurate, and complete examination. A reassuring, confident attitude on the part of the examiner and technical assistant(s) and a calm, educated, and motivated patient contribute to an optimal examination.

The urgency of the clinical situation as well as concurrent medical illnesses may influence the timing of the procedure and the choice of dietary or pharmacologic preparation. Thus, the endoscopist's preprocedure assessment of the patient and review of medical records should include history of medical illnesses, medications, past surgery, previous endoscopies, and history of drug allergies or bleeding tendencies.

To protect the patient's right of self-determination, informed consent should be obtained and documented before the patient is medicated. The endoscopist must discuss what will be done, expected discomfort, potential risks and benefits of the procedure, alternative methods of investigation or management, and the endoscopist should solicit questions.[1,2] Illustrative material which explains the examination in simple terms understandable to the patient and/or an endoscopy assistant who reviews the procedure with the patient helps to assure adequate patient education.

MEDICATION FOR ENDOSCOPY

Medication prior to and during endoscopic procedures may be used to decrease the patient's anxiety or discomfort as well as to diminish gastrointestinal secretions or motility. The guiding principle must be patient comfort and safety. General anesthesia or the presence of an anesthesiologist is rarely indicated except in special circumstances. The amount of sedation or analgesia required for any procedure varies considerably depending upon the patient's age, prior use of medication, associated illnesses, and anxiety level. In all situations, one should use the minimal dose which provides the desired effect. Schedules and routes of administration vary; however, when a prolonged or difficult procedure is likely, an intravenous line allowing titration of dosage and administration of specific antagonists may provide additional safety. The examiner and assistant must remain alert for signs of an unusual reaction to medication. The endoscopy team should be trained in cardiopulmonary resuscitation. Appropriate equipment for resuscitation must be readily available. Trained personnel must assure adequate recovery from sedation or transfer this responsibility, (e.g., to the floor nurse) before the patient is discharged from the endoscopic suite. Instructions should be given to the patient to advise caution in activities requiring alertness until the effect of the medication is completely gone, what to expect after examination, and follow-up instructions, if any. Since the patient may have difficulty remembering instructions after the procedure because of sedation, it is helpful to review these instructions prior to the procedure and/or provide a written set of instructions.

UPPER GASTROINTESTINAL ENDOSCOPY

Patients should ingest no solids for at least 6–7 hours and no liquids for at least 4 hours prior to the procedure. If a gastric emptying problem is suspected, a longer period of fasting may be needed. If circumstances do not permit an adequate fast, lavage of the stomach through a large bore tube can adequately remove stomach contents. For some procedures, topical pharyngeal anesthesia alone is sufficient, especially when the endoscopy is performed with a small diameter endoscope. For prolonged examinations, those in children, or in patients with a high degree of anxiety, rapid onset sedatives and/or analgesics are often necessary. Anticholinergics (e.g., atropine) have been given to decrease saliva, gastric secretions, and motility, and perhaps reduce the likelihood of vasovagal reactions; however, controlled studies of their value as endoscopic premedication do not support their routine use.[3] For procedures in which paresis of

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gastroduodenal motility is necessary, parenteral glucagon may be useful.

COLONOSCOPY

Ideally, the colon should be cleansed of all fecal material before the examination. Patients with a history of chronic constipation or recent barium radiographic examination may require more prolonged preparation. Patients should be instructed to discontinue iron-containing medications in advance of preparation for colonoscopy. Clear liquids, or other residue-free liquid diets for 24–48 hours, followed by cathartics and enemas given until returns are clear, produce an adequately clean colon in most patients. This method demands considerable time and can cause dehydration and hypovolemia when not balanced by adequate oral or intravenous fluid intake.[4] Attention to fluid balance is needed in elderly patients or those with cardiopulmonary or renal disease during this type of bowel preparation. Rigorous chemical purges or cleansing enemas may be impractical or dangerous in debilitated patients, those with partially obstructing colonic lesions, massive lower gastrointestinal bleeding, or inflammatory bowel disease.

An oral purge with 4 liters of a specially balanced electrolyte lavage solution, given at the rate of 1–2 liters an hour, results in adequately prepared colons after a much shorter period of dietary restriction.[5] Preparation solutions (oral lavage or enemas) should not contain mannitol or other fermentable carbohydrates which could be converted to explosive gases because electrosurgery may be performed during colonoscopy.[6] If a patient cannot ingest a large quantity of liquid, nasogastric infusion is a safe, effective alternative method of administration. To prevent excessive sodium absorption, no carbohydrate containing food or fluid should be ingested for several hours before or during the preparation. Ten mg of metoclopramide given about 30 minutes before ingestion of the solution may prevent abdominal distention, sensation of fullness, and the less common nausea and vomiting. Since these solutions do not add to or diminish the circulating blood volume, they should be safe in those with serious systemic illnesses. Oral, whole gut lavage may also be ideally suited for patients with inflammatory bowel disease, other diarrheal illnesses, or lower gastrointestinal tract bleeding.

Discomfort often occurs during colonoscopy, and analgesics and sedatives are usually used. Although anticholinergics have been tried to decrease cardiovascular reactions and reduce colonic spasm, controlled studies have failed to show benefit and use of anticholinergics may result in abdominal distention and prolonged colonic retention of air. Some endoscopists use carbon dioxide as the insufflating agent.

FLEXIBLE SIGMOIDOSCOPY

Effective bowel preparation of the rectum and sigmoid colon can usually be achieved by one or two enemas. A more extensive bowel preparation may occasionally be required in severely constipated patients. Bowel preparation may not be necessary in patients with active colitis or diarrhea and may be inappropriate.

Sedation for flexible sigmoidoscopy is rarely necessary. Small amounts of analgesics and/or sedatives may be required for patients with extreme apprehension or severe perianal disease and for children.

Endoscopic pinch biopsy can be safely performed during flexible sigmoidoscopy. There is no contraindication to performing a barium enema the same day or thereafter following an endoscopic pinch biopsy.[7] Polypectomy should only be performed by experienced endoscopists after as complete a bowel preparation as that for colonoscopy to prevent explosion of combustible gases with endoscopic electrosurgery.

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP)

The patient is prepared as for upper gastrointestinal endoscopy. Because of the longer duration and potential discomfort of the procedure an intravenous line is desirable. If cannulation is delayed, or therapeutic maneuvers prove necessary, repeated doses of sedatives or analgesics may be needed.[8] Careful monitoring of vital signs and level of consciousness is essential throughout and immediately after the examination. Glucagon, with or without anticholinergics administered intravenously, will reduce duodenal motility. Use of iodinated contrast agents for ERCP appears to be safe in individuals with a history of systemic reactions to intravascular contrast agents.[9,10]

When an obstructed duct is suspected, most endoscopists administer antibiotics intravenously prior to the ERCP and continue antibiotics for 24–48 hours if contrast has been instilled into an obstructed system. The benefits of adding antibiotics to contrast solution has not been proven. Depending on the indication for the ERCP, surgical support should be available anticipating possible abdominal surgery.

SPECIAL CONSIDERATIONS

Oxygen administered during the procedure may help patients who have significant hypoxia. For those with heart disease and/or other relevant medical conditions, an electrocardiogram prior to the examination and cardiac and blood pressure monitoring during the examination should be strongly considered. Such monitoring for routine cases is not always necessary.

For most endoscopic procedures, prophylactic antibiotics are not necessary even in patients with vascular or cardiac defects. However, they may prevent endocarditis in those especially at risk—patients with prosthetic valves or a history of prior endocarditis.[11,13] A more thorough discussion of this topic is found in the ASGE guideline entitled *Control of Endoscopically Transmitted Infection.*[14]

Measurement of coagulation parameters is not routinely necessary prior to most endoscopic procedures, but should be performed if there is a history of bleeding diathesis, chronic hepatic, or renal disease, or in hematologic disorders which might interfere with blood clotting.[15] Diagnostic endoscopy is generally safe in patients on anticoagulants; however, the potential for bleeding from biopsy or electrosurgery should prompt temporary discontinuation prior to elective procedures if clinically feasible. Nonsteroidal, antiinflammatory drugs, especially aspirin or other salicylate-containing medications, may increase the risk of bleeding following biopsy or electrosurgery. When practical, these agents should be discontinued for several days before and after procedures involving electrosurgery. The use of electrosurgical equipment for endoscopic therapy is not contraindicated in patients with pacemakers.

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The role of percutaneous endoscopic gastrostomy in enteral feeding

Guidelines for clinical application

The purpose of this statement is to provide a current, practical basis for the use of percutaneous endoscopic gastrostomy (PEG) in patients who require long-term enteral feeding but are unable to maintain sufficient oral intake. The conventional approach to enteral accessin the past was to use nasogastric, nasojejunal, or surgically placed gastrostomy tubes. PEG was introduced in 1980 as an alternative to laparotomy for placement of a gastrostomy.[1-3] PEG is particularly well-suited to patients who have an increased risk for surgery. It can be performed in 15 to 30 minutes, requires minimal, if any, sedation rather than general anesthesia, can be accomplished at the bedside if necessary, has low morbidity, and is successful in over 95% of patients.[4-7]

INDICATIONS

PEG should be considered for pediatric and adult patients who have an intact, functional gastrointestinal tract but are unable to consume sufficient calories to meet metabolic needs. PEG is inappropriate in patients with rapidly progressive and incurable disease, since nasoenteral feedings over a short interval can provide the same result.

The most common indications for PEG are neurologic conditions associated with impaired swallowing and neoplasms of the oropharynx, larynx, and esophagus. Other indications include facial trauma and the need for supplemental feedings in patients with miscellaneous catabolic conditions.[1-7] In patients with repeated aspiration of nasogastric tube feedings or requiring prolonged gastric decompression, PEG can be modified to percutaneous endoscopic jejunostomy to provide both jejunal feeding and gastric decompression.[8,9]

CONTRAINDICATIONS

An absolute contraindication to PEG is the inability to bring the anterior gastric wall in apposition to the anterior abdominal wall. Therefore, patients with prior subtotal gastrectomy, ascites, or marked hepatomegaly require careful evaluation to be sure the stomach and abdominal wall can be brought together with gastric insufflation. Recognition of apposition may be difficult in patients with severe obesity. PEG should not be used for nutritional support when gastrointestinal tract obstruction is present. Relative contraindications to PEG include proximal small bowel fistula, neoplastic and infiltrative diseases of the gastric wall, and obstructing esophageal lesions.[1-7] Coagulation defects, if correctable, are not a contraindication to PEG.

TECHNIQUE

The most widely used technique of PEG is the "pull" method introduced by Gauderer and Ponsky in 1980.[1-3] Modifications of the original technique have been reported. The gastrostomy tube can be pushed rather than pulled into place by a "push" method that has comparable results.[10] In another modification, the "introducer method," the stomach is directly punctured and a Foley catheter placed over a guide wire.[11] Finally, percutaneous gastrostomy has also been described without endoscopy using a nasogastric tube for gastric insufflation, fluoroscopic monitoring, and a direct percutaneous catheter insertion technique.[12]

The basic elements common to all of these techniques are: (1) gastric insufflation to bring the stomach into apposition to the abdominal wall; (2) percutaneous placement of a tapered cannula into the stomach; (3) passage of a suture or guide wire into the stomach; (4) placement of the gastostomy tube; and (5) verification of the proper position.[1-3,10-12]

COMPLICATIONS

Complications of PEG are infrequent, with a mortality rate of 0.3%–1% and morbidity rate of 3%–5.9%

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in the largest reported series.[5-7] A recent literature review of PEG cites an overall complication rate of 17% with only 3% regarded as serious.[6] Reported complications include wound infection, peritonitis, septicemia, peristomal leakage, tube dislodgement, aspiration, bowel perforation, and gastrocolic fistula. Pneumoperitoneum is common after PEG and of no significance, unless accompanied by signs and symptoms of peritonitis.[13] The most common complication is wound infection (5%). There are conflicting data regarding the value of prophylactic antibiotics.[14,15]

COMPARISON OF PEG WITH SURGICAL GASTROSTOMY

Retrospective studies suffer from use of historical controls.[16,17] A single prospective study suggested that advantages of PEG include lower cost, shorter procedure time, and a lower complication rate.[18] However, the overall complication rates of PEG and surgical gastrostomy, when performed on a regular basis, may be nearly equal.[5,16,17]

ENDOSCOPIC PERCUTANEOUS JEJUNOSTOMY

Patients with gastroesophageal reflux are at increased risk for recurrent aspiration of gastric feedings. Modifications of the standard PEG technique allow transpyloric placement of a jejunostomy tube at either the initial or subsequent procedure.[8,9] Feeding can be instituted after fluoroscopic confirmation that the tube is in the distal duodenum or jejunum. Patients with known severe gastroesophageal reflux or gastric motor disorders may benefit from simultaneous aspiration of gastric contents while continuous jejunal feeding is provided.

Patients who develop aspiration during feeding with an existing PEG can have the standard catheter removed, once a fibrous tract is established, and replaced with single or double lumen jejunal tubes.

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Infection control during gastrointestinal endoscopy

Guidelines for clinical application

The purpose of this statement is to provide a current practical basis for the prevention of infection during gastrointestinal (GI) endoscopy and related procedures. In spite of the large number and variety of GI procedures, documented instances of infectious complications remain exceedingly rare.[1] Endoscopic related infection may occur in several situations.

1. Organisms may be spread by contaminated equipment. Bacterial infections (e.g., Salmonella, Pseudomonas) have been acquired in this manner by patients undergoing endoscopy.[2,3] Similar transmission of viral disease is possible given the reported high carrier rates in the population; however, documented cases of endoscopic spread of viruses is either very rare, such as hepatitis B (HBV),[4,5] or unreported as with Human Immunodeficiency Virus (HIV).[6,7]
2. Bacteria may spread, during endoscopy, from the gastrointestinal tract through the blood stream to potentially susceptible tissues or prostheses, possibly resulting in infection (e.g., bacterial endocarditis).[8]
3. Patients with severe neutropenia, immune deficiency syndromes, or those receiving immunosuppressive chemotherapy may be at increased risk for endoscopic transmission of disease.
4. Infected patients may transmit disease to endoscopy personnel.

ROUTINE ENDOSCOPIC CLEANING AND DISINFECTION

A. Cleaning, sterilization, and disinfection: definitions

Cleaning. Cleaning is defined as the physical removal of organic material and/or soil from objects, usually using water with detergents designed to remove rather than to kill organisms.

Sterilization. Sterilization is the act of killing all microbial life and the elimination of bacterial spores. It is most commonly done with heat or ethylene oxide gas.

Disinfection. Disinfection involves the killing of most microorganisms including pathogens and is commonly done with the use of liquid germicides. Definition and classification of chemical germicides vary between the U.S. Environmental Protection Agency (EPA) and the U.S. Public Health Service, Center for Disease Control (CDC). The CDC makes recommendations for the use of chemical germicides in various patient care situations and uses a classification system in which three levels of disinfection are defined: high-level, intermediate, and low-level, depending on the amount and kind of microbial killing involved.[9] High-level disinfection will destroy vegetative microorganisms, tubercle bacilli, and small nonlipid viruses, but not necessarily large numbers of bacterial spores.

The EPA regulates the registration and labeling of various chemical germicides but does not use the above CDC classification of levels of disinfection. Chemical germicides that are registered with the EPA as "sterilants" may be used for sterilization or for high-level disinfection depending on such factors as contact time and frequency of reuse.[6] The specifics of such factors may vary with each product according to the EPA approved labeling. Specific recommendations for disinfection will be found on the label of the individual product container.

B. Mechanical cleaning

The first and most important step in the prevention of infection during endoscopy is mechanical cleaning.[10] This should be done promptly after the use of endoscopes and accessories to avoid formation of concretions. Mechanical cleaning is best done with a nonabrasive detergent or cleaning solution. Enzyme-containing detergents which break down proteinaceous debris or ultrasonic cleaning machines may be useful. The insertion tube is washed with a sponge or cloth. The endoscope tip, biopsy ports (after removing the valves), and less accessible areas are cleaned with a cotton-tipped applicator. All endoscope channels should be brushed to remove particulate matter. Cleaning solution is suctioned or pumped through all channels. Endoscopic accessories are thoroughly cleaned with detergents and brushing of irregular surfaces. After mechanical cleaning, immersible equipment should be thoroughly rinsed with water. Nonimmersible handles should be cleaned with alcohol-dampened cloths and towel dried.

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C. Sterilization and disinfection

Cold gas (ethylene oxide) is effective for sterilizing flexible endoscopes but is impractical for routine use as it usually requires scheduling and up to 24 hours before reuse. Autoclaving will destroy flexible endoscopes. Sterilization can also be achieved by some liquid sterilants if the instrument is immersed completely for specified prolonged exposure times, but this procedure could severely damage flexible endoscopic instruments. For instruments such as GI endoscopes which do not normally come into contact with sterile tissue, sterilization, though acceptable, does not appear to be necessary for safe endoscopy. For these instruments, high-level disinfection with an EPA registered liquid sterilant/disinfectant is appropriate. Treatment other than high-level disinfection (or sterilization) is not acceptable. Chemical germicides that are registered with and approved by the EPA as sterilants can be used either for sterilization or for high-level disinfection depending on contact time specified by the manufacturer.[9] Since the effectiveness of these disinfectants varies with chemical composition, concentration, exposure time, temperature, and number of times used, careful attention should be paid to the manufacturer's label direction for use of the product. It is also important that the disinfectant be safe to apply to the endoscopes, according to the instrument company specifications. Among the acceptable products, gluteraldehyde-based formulations are the most frequently used disinfectants for gastrointestinal endoscopes. Ten-minute exposure/immersion times are typically used and would appear to be sufficient to kill those infectious agents likely to be encountered in GI endoscopy. Again, immersion times and other specifics for disinfection may vary according to the individual product label specifications. Information for specific label claims for the various disinfectants can be obtained by writing to the Disinfectants Branch, Office of Pesticides, EPA, 401 M Street SW, Washington, DC 20460. The efficacy of cleaning and disinfection is personnel-dependent. Good technique and adherence to time schedules are important.

After each procedure, gastrointestinal endoscopes should be thoroughly cleaned and then soaked in a chemical sterilant/disinfectant according to the chemical manufacturer's directions and exposure time necessary to achieve disinfection. Following disinfection, endoscopic equipment must be rinsed free of residual germicide and dried. A tap water rinse for 30 seconds has been shown to remove gluteraldehyde effectively from disinfected equipment, but residual odor may require a longer rinse and aeration time. Endoscopic accessories that may be heat-stable, such as biopsy forceps and cleaning brushes, should be thoroughly cleaned; then sterilization by autoclaving after each use should be strongly considered. Certain accessories such as sphincterotomes, ERCP cannulas, and sclerotherapy needles are disposed of or cleaned, dried, and gas sterilized after use. The water bottle will need to be disinfected on a regular basis.

D. Forced air drying and storage

A critical part of the cleaning and disinfecting process involves forced-air drying of the endoscope channels prior to storage. At the end of the day, endoscopes should be dried with forced-air according to the manufacturer's recommendation. This process is important to prevent proliferation of residual bacteria and fungi during storage, and is even necessary following washing and disinfection with automated machines. It has been recommended that 70% alcohol be suctioned through all channels of ERCP endoscopes prior to forced air drying and storage.[3] A sterile water rinse or alcohol rinse should be performed prior to forced air drying and prolonged storage of flexible endoscopes. Endoscopes should be stored hanging rather than coiled in their boxes.

Endoscopic washing machines may offer advantages such as automating washing and disinfection cycle times, freeing endoscopy assistants for other patient care duties, and decreasing exposure of endoscopy personnel to contaminated equipment and disinfectants. However, these machines may not assure a clean, disinfected endoscope and instances of contamination have been reported. It should be remembered that mechanical cleaning and brushing of the suction channels must be done prior to placing the endoscope in the washing machine.

ENDOSCOPE STERILIZATION AND DISINFECTION IN SPECIAL SITUATIONS

A. Infected patients

There is evidence, by direct infectivity testing, that HBV is inactivated by a 10-minute gluteraldehyde exposure[11] and that HIV is inactivated rapidly after being exposed to commonly used chemical germicides at concentrations that are much lower than used in practice.[6] However, at present, no EPA registered disinfectant may claim to be effective for inactivating HBV or HIV. The CDC states that standard sterilization and disinfection procedures for patient care equipment currently recommended for use are adequate to sterilize or disinfect instruments contaminated with pathogens including HIV.[6,12] Thus, following endoscopic procedures on infected patients, the instrument should be cleaned and then receive routine high-level disinfection. Gas sterilization is another option in these cases. "Dedicated" instruments are not necessary.

B. Immunocompromised patients

Severely immunocompromised patients have an increased susceptibility to infection by a wide variety of microorganisms. Endoscopes should receive high-level disinfection or be sterilized prior to the procedure. Biopsy forceps should be sterilized; water bottles, and other accessories should also be disinfected or sterilized and sterile water should be used in the water bottle.

ANTIBIOTIC PROPHYLAXIS FOR GASTROINTESTINAL ENDOSCOPIC PROCEDURES

Bacterial endocarditis is a serious, often life-threatening infection, presumably resulting from bacteremia in an individual with a susceptible cardiac lesion. However, about half the patients who develop endocarditis do not have a recognized or recognizable predisposing cardiac lesion.[13] The occurrence of endocarditis following gastrointestinal procedures is rare, with only a few cases reported.[13,14]

Even though patients undergoing gastrointestinal procedures with a high incidence of bacteremia may be at increased risk for developing endocarditis, there are no firm data that have clearly established the benefit of using prophylactic antibiotics for any procedure. No controlled clinical trials establishing the efficacy of antibiotics in preventing endocarditis have been performed, and because such a large number of patients would be required, it is unlikely they will ever be carried out. However, because patients with prosthetic heart valves and those with surgically constructed systemic-pulmonary shunts appear to be at especially high risk, and because endocarditis in a patient with a previously infected valve is so disastrous, antibiotic prophylaxis is recommended in these situations.[15] The physician who performs endoscopic procedures should be aware that the Committee on Rheumatic Fever and Infective Endocarditis of the American Heart Association has recommended that antibiotics be considered in situations other than those mentioned specifically above.[15] Differences of opinion are not unexpected when limited data are available.[13,14]

The traditional antibiotic regimen for prophylaxis against endocarditis for gastrointestinal procedures has been ampicillin plus an aminoglycoside given parenterally. For patients allergic to penicillin, vancomycin plus an aminoglycoside has been the usual suggestion. The value of a post-procedure dose is unknown and its use is optional.[15] There has been increasing interest in the use of oral amoxicillin as an alternative to parenteral antibiotics for certain procedures. The advantages and disadvantages are discussed in a review article.[13]

There has been some support for employing antibiotic prophylaxis selectively for some gastrointestinal procedures and not for others. Some reports have suggested that the incidence of bacteremia is particularly high with certain procedures (e.g., injection sclerotherapy), but other published reports differ.[16-18] Not only is the decision about whether to use antibiotics made difficult by this conflicting data, but the physician must also appreciate that the organisms associated with bacteremia for a certain procedure (e.g., injection sclerotherapy) may be different than the organisms for which the standard prophylactic antibiotics (ampicillin plus an aminoglycoside) are chosen.[9]

The question about whether to use antibiotic prophylaxis to prevent infection in prosthetic devices other than heart valves is also controversial.[20] Most device-associated infections seem to occur as a result of the inoculation of organisms at the time of insertion of the device, not because of subsequent bacteremia. Device-associated infections are often caused by multiple organisms, and prophylaxis with drugs commonly used for natural valve endocarditis cannot be presumed to be effective.

From the foregoing discussion it is apparent that the decision as to whether or not to use antibiotic prophylaxis for gastrointestinal procedures is complicated. For patients with prosthetic heart valves, surgically constructed systemic-pulmonary shunts, and a previous history of endocarditis, antibiotic prophylaxis is recommended. For other situations, their use is optional and the physician's decision will be based on his or her interpretation of the existing data, specific aspects of the individual clinical setting, and discussion with the patient.

PROTECTION OF PERSONNEL

Endoscopy personnel should be made aware of the dangers of contaminated equipment and the modes of disease transmission. They should understand that a patient's infectious status may be unknown at the time of endoscopy. It is therefore prudent to apply the same precautions generally. Preventive measures include using gloves when coming into contact with contaminated endoscopic equipment and patient secretions, blood, or stool. Preventive measures may also require gowns, masks, and eye-coverings when performing procedures involving splattering or more extensive contact with blood or potentially infectious fluids.[6] Needles should be discarded in safe containers *without* recapping in order to avoid inadvertent sticks. Following the procedure, exposed surfaces should be thoroughly cleaned of visible contaminants and then disinfected with an EPA-registered hospital disinfectant. In addition, handwashing should be done before and after each patient interaction, irrespective of whether gloves are worn. Infected patients may be endoscoped at the bedside as the clinical situation warrants.

The risk of acquiring hepatitis B infection by endoscopy personnel is small[21]; however, with the availability of an effective and safe hepatitis B vaccine, endoscopy personnel should be offered immunization.

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Therapeutic Gastrointestinal Endoscopy

American Society for Gastrointestinal Endoscopy

An Information Resource Manual

An Information Resource Manual

Therapeutic Gastrointestinal Endoscopy

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Endoscopic Treatment Of Bleeding From The Gastrointestinal Tract

Therapeutic Gastrointestinal Endoscopy

INTRODUCTION

Over the past two decades, gastrointestinal endoscopy has evolved into an extremely valuable diagnostic modality. Using modern instruments, well-trained skilled examiners are able to quickly and accurately define the cause of signs and symptoms of many important diseases of the alimentary tract, pancreas, and biliary system. Recently, the value of endoscopy has been greatly extended by the development of a variety of techniques which allow the endoscopist to treat much of the disease he or she encounters. In many instances, these therapeutic applications of gastrointestinal endoscopy can be used in patients who are too ill to tolerate surgical alternatives. In others, endoscopic treatment of low risk patients may completely obviate the need for surgery, general anesthesia, prolonged hospitalization and extended convalescence, thus providing considerable savings in both patient discomfort and inconvenience, and in health care resources.

The development of therapeutic endoscopy has been so rapid that many of the procedures are not adequately described and discussed in available textbooks or current medical periodicals. Thus, many health care providers and related private and governmental health care agencies are unaware of their existence or their potential.

The purpose of this manual is to provide an up-to-date review of currently practiced therapeutic endoscopic procedures, to be used as an information resource by physicians, other health care providers, and all related agencies that deal with health care issues. The manual was sponsored by the American Society for Gastrointestinal Endoscopy (ASGE). Each of the 15 papers comprising the manual were written by individual ASGE members who are expert in the technique or procedure discussed. They have based their reviews, conclusions and recommendations entirely on their own knowledge and experience plus their individual interpretation of pertinent literature. The manual has not undergone extensive review by other authorities in endoscopy who may not agree with some of the points presented by these authors. Therefore it cannot be considered a consensus opinion, endorsed by ASGE, similar to other published society guidelines.

Each paper is divided into the following sections: Introduction, procedure description, equipment description, indications and contraindications, utilization, results, and cost analysis. In order to present concise statements not all clinical situations or variations encountered in practice are discussed. Some of the conclusions, therefore, may apply mainly to the examples included in the review, and actual clinical considerations may justify a course of action at variance with these recommendations.

The cost analyses are intended as a rough comparison between the cost of the therapeutic endoscopic procedure and the most commonly employed surgical alternative. These comparisons are rough estimates based on local health cost data, and should be considered largely illustrative, rather than exhaustive considerations of cost. The examples presented may not include all costs and may not adequately consider variations in patient risk, severity of disease, or the cost of therapeutic failures and complications. Rigorous prospective cost-benefit comparisons would be preferable; however, at the present time the necessary methodology and cost data are not adequate to allow for this analysis.

To assist readers with nonmedical backgrounds, an extensive glossary of medical terms is appended to the manual.

Prepared under the direction of the
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Control of Upper Gastrointestinal Bleeding by Monopolar Electrocoagulation

JOHN P. PAPP, M.D.

PROCEDURE DESCRIPTION

During the evaluation of a patient with gastrointestinal bleeding with the flexible fiberoptic endoscope, an ulcer with a bleeding or nonbleeding artery ("visible vessel" with or without a fresh clot) may be found. Through the endoscope's 3-4mm biopsy channel, a monopolar electrode may be passed under direct vision to the artery for application of treatment. The monopolar electrode is a hollow circular tube 2mm in diameter with a metal cap on its end of 4mm in length. A wire extends from the power source via the hollow center of the electrode to the metal cap and conveys electrical energy when activated by the physician via a foot pedal. The power source can be adjusted as to the duration and amount of energy delivered.

The monopolar electrode is placed near the artery in the ulcer and activated. Moving the electrode circumferentially around the artery and applying electrical energy generates heat and produces coagulation of the vessel. The term used for this process is "*electrocoagulation*".

EQUIPMENT

The monopolar electrode became available for use in the early 1970's. After a decade of experimental and clinical research, it is now widely available for endoscopic electrocoagulation. It can be used with power sources available in all endoscopy suites.

INDICATIONS AND CONTRAINDICATIONS

Monopolar electrocoagulation is indicated in the treatment of active bleeding from ulcers in the esophagus, stomach, and duodenum[1]; in the treatment of a visible nonbleeding vessel[2]; for angiomata in the upper and lower intestinal tract[3]; and for bleeding Mallory-Weiss tears[4].

Contraindications include bleeding from esophageal or gastric varicies and massive bleeding that prevents adequate visualization of the bleeding site.

UTILIZATION

It is estimated that more than 150,000 patients will be admitted for active gastrointestinal bleeding to acute care hospitals. Mortality increases dramatically in patients over 50 years of age (over age 50: 12%, over age 60: 15%, over age 70: 19%, over age 80: 23%)[5]. As older patients have more categories of associated disease such as heart, kidney, lung, etc., and bleeding, their mortality increases (1 category - 9.2% mortality, 2 categories - 9.9%, 3 categories - 14.6%, 4 categories - 27%, 5 categories - 44% mortality)[6]. If patients over the age of 50 with active bleeding are treated medically, and surgery is delayed for more than 8 days, mortality increases from 12% to 52% (5). Mortality from emergency surgical gastrectomy ranges from 1% in patients less than 50 to 44% in those over 80 (over 50: 22%, over 60: 26%, over 70: 30%, over 80: 44%)[5].

In uncontrolled studies in the United States, monopolar electrocoagulation successfully stopped bleeding from 88% of lesions. Not only was monopolar electrocoagulation successful, but cost, length of hospitalization, and mortality were significantly reduced[1,2,3,7]. Mortality for those patients over 60 was 7.4%, compared to predicted 15 -50%.

Hospital stays for successfully electrocoagulated Mallory-Weiss tears was 18 days shorter and cost an average of $4,756 less in 1974-1976 than cases treated surgically. Similarly, the hospital stays of gastric ulcer patients were 5 days less and their cost averaged $668 less. Patients with marginal ulcers remained in the hospital 11 days less and the cost of hospitalization averaged $3,465 less. Patients with duodenal ulcers undergoing electrocoagulation were in the hospital 1.5 days more than those treated surgically but the average cost was $1,062 less[3,7].

In a controlled trial of patients with a nonbleeding visible vessel, Papp[2] randomized 32 patients into either medical or monopolar electrocoagulation treatment. Fifteen of 16 patients had no rebleeding in the electrocoagulation group. Thirteen of 16 patients with the visible vessel treated medically rebled. There was significant reduction in length and cost of hospitalization with electrocoagulation. Gastric and duodenal ulcer patients successfully electrocoagulated (93%) were in the hospital 8.3 days at an average total cost of $3,869 in 1979-1981. Patients in the medically treated control group who rebled were in the hospital an average of 18.5 days for a cost of $8,154. Thus, immediate monopolar electrocoagulation saved 10.2 days hospitalization and $4,285 in costs.

Physician fees were not included in the above data, but would be considerably less, as shown in TABLE 1. Table 1 shows actual comparative charges for 2 patients age 63 with actively bleeding duodenal ulcers treated in December, 1985.

Control of Upper Gastrointestinal Bleeding by Monopolar Electrocoagulation

JOHN P. PAPP, M.D.

TABLE 1

	Electrocoagulation	Surgical Treatment
Length of stay	6 days	7 days
Physician Fee	$861	$1,200
	Anesthesiologist	402
Total Physician Charge	**$861**	**$1,602**
Hospital Charges		
Room	1,785	2,275
	(1 day ICU)	800
EKG	30	30
Lab	600	1,187
X-ray	160	160
Op Room	-0-	1,338
Recovery Room	-0-	80
Drugs and IV Solutions	450	877
Blood	135	1,041
GI Lab	75	-0-
Respiratory Therapy	-0-	125
Total Physician and Hospital Charges	**$4,096**	**$9,515**

CONCLUSION

In the hands of a skilled endoscopist, treatment of gastrointestinal bleeding with monopolar electrocoagulation is both safe and effective, and it reduces mortality and the length and cost of hospitalization.

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Endoscopic Treatment Of Bleeding From The Gastrointestinal Tract

Ulcer Hemorrhage — Laser Treatment

BERGEIN F. OVERHOLT, M.D.

INTRODUCTION

Peptic ulcer disease occurs in 10% of the population in this country, producing significant morbidity and mortality and contributing greatly to the costs of health care. Bleeding is the most common complication of ulcer disease and either fails to stop spontaneously or recurs in about 20% of patients, requiring some form of therapeutic intervention.

In the past, emergency surgery was the only treatment available to control ulcer bleeding in these patients. Recently, characteristics of the ulcer have been identified during diagnostic endoscopy that are associated with a much higher rate of persistent or recurrent bleeding, and endoscopic methods of hemostasis have been developed that can control ulcer bleeding. Laser therapy is one of these endoscopic techniques and represents a reasonable alternative to emergency surgery in selected patients, particularly those with stigmata of recent hemorrhage, either producing permanent cessation of bleeding or allowing time to stabilize the patient's clinical status so that surgery, if required, can be performed electively, under optimal conditions.

PROCEDURE DESCRIPTION

Flexible fiberoptic endoscopes have built-in channels that provide a vehicle to carry flexible quartz probes to a specific point in the upper gastrointestinal tract, in this case to a specific bleeding point in a peptic ulcer. The quartz fibers can conduct light energy from Argon or Nd:YAG (neodymium:yttrium, aluminum and garnett) lasers. The energy from these lasers is converted to heat when the light beam "hits" tissue. The heat is then used to coagulate the bleeding site. When the procedure is successful, 1) bleeding is stopped, 2) the need for transfusions is lessened, 3) the need for emergency surgery is reduced, 4) the length of hospitalization is probably reduced, and 5) the mortality rate is reduced.

EQUIPMENT

The current diagnostic and therapeutic endoscopes in common use generally meet the needs for laser therapy of ulcer hemorrhage. Both single- and double-channel instruments find use according to the specific needs of each clinical situation. The adequately prepared laser endoscopist should have both types of instruments available to allow the flexibility needed to properly treat the life-threatening problem of ulcer hemorrhage. These instruments represent significant advancements in therapeutic endoscopy that were not available even as recently as five years ago.

The adaptation of lasers to flexible endoscopy is a recent technological advancement made possible through the development of flexible quartz probes small enough to pass through the endoscope's channels. Since the quartz crystal will transmit the light energy of the Argon and Nd:YAG lasers, the utilization of lasers to treat ulcer hemorrhage became a reality in the late 1970's. Only in the last 4 to 5 years has this technology been available to the trained endoscopist, and only in the last several years has its use become reasonably widespread.

The result — endoscopic laser therapy of ulcer hemorrhage — represents a significant technological advance in the treatment of a major, life-threatening human illness.

INDICATIONS AND CONTRAINDICATIONS FOR LASER THERAPY OF ULCER HEMORRHAGE

Indications for laser photocoagulation generally follow those of endoscopy in patients with ulcer hemorrhage. If endoscopy is indicated and feasible, laser therapy can be considered. In most situations for patients with torrential bleeding which cannot be cleared adequately for visualization, emergency surgery is indicated. With lesser degrees of bleeding, attempts at laser therapy are indicated. Those patients with stigmata of recent hemorrhage (SRH), including 1) active bleeding, 2) a visible vessel ("sentinel clot") or 3) a fresh clot, are ideal candidates for laser photo-coagulation. The large, visible gastroduodenal artery should be approached with great caution if at all.

UTILIZATION

Estimates are that some 150,000 to 200,000 admissions to acute care hospitals occur annually for upper gastrointestinal (UGI) hemorrhage. The majority of these are for ulcer hemorrhage. In spite of the improved diagnostic capabilities of endoscopy, mortality from all causes of UGI hemorrhage approximates 10% of cases. These figures, of course, include patients with other serious physical illnesses in which ulcer hemorrhage represents only one contributory factor toward death.

Medical research has detected a select group of patients with ulcer hemorrhage that are particularly prone to continue bleeding or to rebleed, circumstances in which mortality rates are significantly higher. Such patients demonstrate the "stigmata of recent hemorrhage" (SRH), described above. It is in controlled studies of patients with SRH that laser therapy has been proven to be an effective form of

Endoscopic Treatment Of Bleeding From The Gastrointestinal Tract

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treatment that reduces the number of transfusions needed, the incidence of emergency surgery and the mortality rate.

RESULTS OF ENDOSCOPIC THERAPY

Cessation of ulcer hemorrhage is the ultimate goal of laser therapy of this life threatening situation. Other desirable results include reduction in transfusion requirements, the need for emergency surgery, length of hospitalization and, of course, mortality. Controlled and uncontrolled clinical studies indicate that these goals are being achieved with laser therapy of ulcer hemorrhage. Generally, 70-100% of patients treated with laser therapy have had cessation of bleeding, a significant improvement over the natural history of the disease process. Likewise, significant reductions in transfusion requirements, emergency surgery and mortality have been achieved.

Complications of laser therapy of ulcer hemorrhage include primarily laser-induced hemorrhage (5-30%) and perforation (1-2%). As expected, as the endoscopist's experience with laser therapy increases, the incidence of complications declines.

COST ANALYSIS

Due to the complexity of medical and surgical illnesses, it is difficult to obtain a representative cost analysis. However, the case presented herein represents a clear example of an admission for severe ulcer hemorrhage that was treted successfully with the laser.

> M.B., 44 y/o WF, was admitted to the hospital ICU with two days of melena, marked weakness and postural hypotensive symptoms. Hematocrit was 21.6. At endoscopy, a visible vessel (sentinel clot) was located centrally in the base of a 1.5cm antral ulcer. Laser therapy was carried out and there was no rebleeding. A total of 4 units of blood were required to raise her hematocrit to 31.

The case presented to represent surgical therapy actually represents a medical failure in the treatment of a bleeding duodenal ulcer.

> P.R., 50 y/o WM, was admitted to the hospital with melena and weakness. Hemotocrit was 27. At endoscopy, a pyloroduodenal ulcer found 6 weeks previously was again noted. Because of persistence of the ulcer and recurrent bleeding in spite of diet, antacids and cimetidine, surgery was performed on the third hospital day. Only one unit of blood was given to raise the hematocrit to 30.

TABLE 1 represents actual comparative charges for the two patients:

TABLE 1

	LASER	SURGICAL
Length of Stay	5 days	10 days
Physician Fee		
Gastroenterologist	$ 880.00	
Surgeon		$1,250.00
Anesthesiologist		462.00
Total MD Charge	$ 880.00	$1,712.00
Hospital Charge		
Room	819.25	1,440.00
Echocardiogram	243.00	
Lab-Clinical	678.25	472.15
(includes blood T&C, administration, etc.)		
Cardiac Monitor	94.50	
X-Ray	178.00	130.00
Endoscopy Room (Laser)	450.00	
Anesthesia Supp.	-0-	149.00
Operating Room	-0-	700.00
Recovery Room	-0-	110.00
Drugs	98.90	36.60
Drugs - Injected	238.80	1,004.85
Blood	160.00	48.00
IV Solutions	184.15	232.80
Med. Supp.	126.10	464.55
Surg. Supp.	350.00	625.10
Inhal. Ther.	-0-	3.00
Total Hospital Charge	$3,620.45	$5,330.55
Total MD & Hospital Charge	$4,500.45	$7,042.55
Length of Hospital Stay	5 days	10 days

COST BENEFIT

A Comparative cost-benefit analysis between laser therapy and surgical therapy of ulcer hemorrhage is difficult to obtain due to the complexities of comparative analysis in patients who vary so greatly in age, severity of associated illnesses, etc. Based on the above case studies however, successful laser therapy is significantly less costly in terms of dollars and time. Additionally, the longer recovery time for surgical intervention, the greater incidence of postoperative morbidity and mortality, and the greater loss of time from work following surgery clearly favor laser therapy. It should be pointed out that those patients requiring surgry generally are more severely ill than those who can be managed by therapeutic endoscopy, again making it most difficult to develop a true cost benefit analysis. However, if laser therapy is successful, total costs and lost time from work are clearly less than if surgery is necessary.

Ulcer Hemorrhage — Laser Treatment

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Ulcer Hemorrhage — BICAP Probe Treatment

ROBERT L. PROTELL, M.D.

INTRODUCTION

The development of flexible fiberoptic endoscopes with built-in internal channels allows the operator access to the gastrointestinal tract for possible endoscopic therapy. Over the past decade, this theoretical potential has become a reality. One of the areas in which endoscopic therapy has begun to impact on our care of patients is peptic ulcer hemorrhage. There are currently several methods available to staunch bleeding from peptic ulcers using the endoscope. One of these is the BICAP Probe.

PROCEDURE DESCRIPTION

Endoscopic BICAP probe therapy consists of passing a specialized hemostatic bipolar electrode through an endoscopic channel, sighting the precise bleeding point, and coagulating this point using one of several techniques. The two most frequently used BICAP coagulation techniques are: 1) direct application of the BICAP Probe to the bleeding point, and 2) circumferentially coagulating around the bleeding point prior to a direct application. Successful coagulation of ulcer bleeding converts an emergent situation to an elective one. Not only does the acute bleeding episode cease, but decisions regarding additional therapy can be made in a setting that is most conducive to optimum patient outcome. For example, emergency surgery for peptic ulcer hemorrhage carries a mortality rate of 10-20% in patients over the age of 60. Elective ulcer surgery in the same age group has 1-2% operative mortality rate. Utilizing BICAP Probe hemostasis, it may be possible to obviate the need for any surgical intervention.

EQUIPMENT

Optimal treatment of peptic ulcer hemorrhage with this technique requires a flexible fiberoptic endoscope with a large channel or with two channels. A standard single-channel endoscope (2.8mm channel) is acceptable if ulcer bleeding is not too brisk. The BICAP Probe itself consists of a cylindrical tip 7mm long containing three pairs of electrical contact points arranged to permit good tissue contact by electrodes of opposite polarity at all angulations. BICAP Probe tips are available in 7Fr and 10Fr diameter sizes; both connect to a specialized radio frequency bipolar generator with 50 watt power output. The probes currently sold are considered disposable. It is common practice, however, to reuse the probes after ethylene oxide gas sterilization between procedures. The probes cost $150 apiece; the special electrosurgical generator costs approximately $4,500.

INDICATIONS AN CONTRAINDICATIONS

The goal of BICAP therapy for ulcer hemorrhage is hemostasis. If endoscopy is feasible, in a given case, BICAP treatment of bleeding peptic ulcers is also theoretically possible. Absolute contraindications for attempted BICAP coagulation are inadequate visualization of the bleeding site due to massive hemorrhage or inopportune location of the bleeding ulcer, and free peritoneal air. Brisk bleeding or oozing from a peptic ulcer that is well visualized, and peptic ulcers with stigmata of recent hemorrhage, including a visible vessel or a fresh clot, are optimal candidates for BICAP Probe therapy.

UTILIZATION

The mortality from upper gastrointestinal hemorrhage has remained approximately 10% for the past four decades. This should not be surprising because, until recently, endoscopic therapy such as BICAP Probe coagulation has not been available.

There are between 50 and 100 hospital admissions per 100,000 adult population annually for upper gastrointestinal hemorrhage. This translates to approximately 100,000-200,000 admissions per year in the United States. The majority of this bleeding is from peptic ulcers. Because emergent endoscopy is able to locate the bleeding site in 90% of patients, ulcers that are actively bleeding or that display stigmata of recent hemorrhage as defined above are candidates for BICAP Probe treatment. While controlled studies are not available, clinical data to date suggests that BICAP Probe coagulation of bleeding peptic ulcers is effective in reducing transfusion requirements and the need for emergent surgery.

RESULTS OF THERAPY

The goal of BICAP Probe treatment is cessation of ulcer hemorrhage. As stated earlier, reduced transfusion requirements, decreased need for emergent surgery, reduction in hospital stay, and lower mortality are the therapeutic goals. These objectives have not been demonstrated in randomized studies comparing BICAP Probe coagulation to standard surgical treatment of bleeding peptic ulcer. However, other endoscopic coagulation techniques like laser photocoagulation have been compared to surgery for bleeding ulcer and have been proven superior with respect to mortality, units of blood transfused and cost (excluding the initial cost of the laser).

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ROBERT L. PROTELL, M.D.

COST ANALYSIS AND BENEFIT

The variation among patients makes it impossible to draw hard conclusions from comparisons of different therapies in a non-study situation. Nevertheless, to the routine cost of a daily hospital stay, gastrectomy and vagotomy can be expected to add the following:

Operating Room Fee	$1,500-$2,000
Recovery Room	300
Anesthesia	$1,000-$1,500
Surgeon	$2,000-$2,500
Additional Intensive Care Unit (3-4 Days)	2,225
Total Length of Hospital Stay (barring complications)	7-10 days

The patient whose bleeding ulcer is treated with the BICAP Probe for hemostasis has these additional costs to his/her hospital stay:

Intensive Care Unit (1-2 days)	$ 775-$1,500
Endoscopy Room Use Fee	280
Endoscopy Professional Fee	495
Average Length of Stay	5 days

This information is based on approximations from several patients in each category of therapy.

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Ulcer Hemorrhage — Heater Probe Treatment

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PROCEDURE DESCRIPTION

Heater probe coagulation is one of several hemostatic treatments that can be applied through the endoscope to control bleeding peptic ulcer hemorrhage. After stabilization of the bleeding patient, endoscopic examination of the upper gastrointestinal tract is performed using minimal sedation. Even when hemorrhage is active, with experience, the endoscopist can find the site of bleeding in the upper gastrointestinal tract in over 90% of cases. With a large amount of blood in the stomach, the task of finding the bleeding point can be facilitated by moving the blood pool with position changes or by suction. After the general area of bleeding has been determined, water irrigation from the heater probe washes overlying blood away from the ulcer base so that the exact point of active or recent hemorrhage can be found. The heater probe is then pressed directly against the bleeding point to compress the vessel and tamponade its blood flow, at which time heat is applied to seal or weld the vessel permanently closed (coaptive coagulation). This procedure is typically performed under local anesthesia at the bedside in the ICU or in the endoscopy unit. length of time of the procedure varies considerably from case to case, but averages about 40 minutes.

EQUIPMENT

Equipment used for heater probe coagulation includes an endoscope and the heater probe unit. A special therapeutic endoscope with one or more large channels for suction and instrument passage is required for this procedure. Each year, these therapeutic endoscopes are further improved with regard to flexibility, maneuverability, decreased outer diameter, increased channel size and improved optics.

The heater probe device, is a self-contained unit which includes a computer-controlled power supply, an irrigation system, and the probe catheter which is passed down the endoscopic channel. The heater probe tip contains a miniaturized heating coil within a metal capsule which is coated with teflon to prevent probe adherence to the tissue. Heating is precisely regulated by a thermometer in the tip that feeds back to the computerized power source. Advantages of this device include its effectiveness with arterial coagulation, relative safety due to absence of potential for acute thermal erosion, portability, and relatively low cost. Although the heater probe was only recently marketed for clinical use, its introduction was preceded by a decade of research to perfect this sophisticated device.

INDICATIONS AND CONTRAINDICATIONS

Patients who have bled enough to be considered for emergency surgery are candidates for this less invasive procedure. Additionally, there is great interest currently in trying to define criteria to predict, early in the hospital course, which patients will rebleed so that they may be treated before rebleeding. The endoscopic appearance ("visible vessel", etc.) and bleeding severity are helpful features; studies are in progress to define precise guidelines for patient selection for this endoscopic therapy.

Absolute contraindications for endoscopic hemostasis are few, mainly including the combative patient and the rare patient with torrential hemorrhage who requires immediate surgery. If the clinical situation demands, very high risk patients who are poor surgical candidates can be endoscoped and treated successfully.

UTILIZATION

In the United States, there are over 100,000 patients per year with bleeding peptic ulcers. Traditionally, emergency surgery has been required for the 15% of patients who continue to bleed despite conservative therapy. Emergency surgery in this setting carries a high mortality rate (15-30%). Peptic ulcer hemorrhage places a strain on blood banks, and multiple transfusions increase the risk of hepatitis. In the past, a significant percentage of bleeding ulcer patients also required subsequent elective surgery. However, with the striking improvements in our medical therapy, most ulcers can now be healed without surgery if the acute bleeding is controlled.

RESULTS OF ENDOSCOPIC THERAPY

The aims of endoscopic hemostatic therapy are to shorten the bleeding episode and avoid rebleeding with its attendant high morbidity and mortality. Treatment goals also include a reduced need for transfusion and surgery, as well as shortened hospitalization and reduced cost. To properly address these goals with the new heater probe device, controlled comparison with standard therapy is needed (currently in progress).

The reported effectiveness of a single heater probe treatment is approximately 80%. Efficacy increases to over 90% with repeat heater probe treatment for ulcers which rebleed. The ability to retreat with relative safety is a strong advantage for this type of endoscopic therapy.

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The complication rate with the heater probe is very low. Perforation has not yet been reported, and induced hemorrhage uncontrolled by further heater probe treatment is rare. In contrast, surgical therapy for bleeding peptic ulcer carries a mortality rate of 15-30%.

COST ANALYSIS

There are no published data comparing the cost of endoscopic heater probe (HP) therapy and surgery for bleeding peptic ulcer. As a "best estimate", the following calculation can be made:

Cost estimates:

HP treatment (including physician and hospital charges)	$ 850
2 HP treatments	1,450
Surgery (including surgeon, anesthesia and hospital charges)	3,000
Surgery and diagnostic endoscopy	3,500

For each 1000 patients who receive traditional therapy, 150 will need emergency surgery.

	n	cost
Surgery (+ diagnostic endoscopy)	150	$525,000

For 1000 patients who receive the option of endoscopic HP therapy, 200 would be selected (assuming 75% accuracy of selection using "major" hemorrhage and "visible vessel" as criteria).

	n	cost
Unsuitable; surgery needed	10	$ 35,000
1 HP treatment successful	152	129,200
2 HP treatments successful	25	36,430
2 HP treatments unsuccessful; surgery needed	13	59,520
	200	$260,150

Thus, the cost of invasive therapy with the endoscopic heater probe option is estimated to be *half* that of the traditional surgical approach. Additional savings will result from reduced length of hospitalization with successful heater probe treatment (5 days) as compared to surgery (10 days).

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Gastrointestinal Angiomata: Current Diagnosis and Treatment

DENNIS M. JENSEN, M.D.

INTRODUCTION

Acute or chronic gastrointestinal (GI) bleeding and iron deficiency anemia may result from GI angiomata. The term GI *angioma* (plural *angiomata*) will be used in this paper to describe abnormal mucosal and submucosal blood vessels. The endoscopic appearance varies but most angiomata are flat, red, *arteriovenous malformations*. Other synonyms are *telangiectasia, angiodysplasia, and ectasia*.

GI angiomata are occasionally incidental findings on routine upper gastrointestinal endoscopy or colonoscopy. However, GI angiomata located anywhere in the gut can result in painless GI hemorrhage, which is the most common presentation for medical attention. The severity of the bleeding varies in different patients from occult to very severe. In a referral population of patients with GI angiomata, the GI bleeding is often recurrent and severe. Multiple hospitalizations, radiologic and gastroenterologic evaluations, and multiple transfusions characterize these patients' medical history. Before the advent of endoscopic hemostasis, supportive medical care and surgical resection of the affected bowel segment were the standard therapeutic alternatives for patients with bleeding GI angiomata.

The etiology of GI angiomata is unknown but several associated conditions have been recognized. These include increased age, valvular heart disease, renal failure, cirrhosis, previous gut radiation, collagen-vascular syndromes and Osler-Weber-Rendu (OWR) syndrome (hereditary hemorrhagic telangiectasia). The OWR syndrome is easily recognizable because most patients have a positive family history; telangiectasia of the mucous membranes, tongue, and skin and documented GI bleeding from upper gastrointestinal angiomata. However, most patients with GI angiomata do not have the OWR syndrome and will be referred to as non-OWR angiomata in this paper. The mean age of angiomata patients is 65 years and 80% have some predisposing condition for GI angiomata.

The incidence of the OWR syndrome in the general populations is about 5 in 100,000. About one-third of these patients have severe enough GI bleeding during their lifetime to be treated. There are no accurate estimates of the prevalence of non-OWR angiomata in the general population. Non-OWR angiomata are much more common than OWR angioma. In our referal populations at UCLA and Wadsworth VA Hospitals, the ratio has been 6 to 1.

Non-bleeding angiomata *(angiodysplasia)* have been reported as a common finding in surgically resected cesums and right colons of elderly patients when careful histologic studies have been performed. Most of those patients did not have previous GI bleeding. The prevalence of UGI angiomata as a source of severe UGI bleeding was 6-9% at Wadsworth VA Hospital and UCLA Hospital. For adult patients with severe lower GI bleeding requiring intensive care unit treatment, colonic angiomata were the most common source of bleeding, representing 30% of the total. Colonic angiomata are also a common cause of less severe bleeding and iron deficiency anemia, particularly for patients older than 60 years.

PROCEDURE DESCRIPTION — ENDOSCOPIC DIAGNOSIS AND COAGULATION

Most patients have GI angiomata diagnosed after they present for medical attention because of GI bleeding. The endoscopic appearances of angiomata, although variable, are familiar to most gastroenterologists. Upper tract endoscopy and colonoscopy are now considered the most sensitive and specific means of diagnosis. Endoscopic biopsies are often non-diagnostic because of crush artifact, shrinkage and fixation, and/or failure to reach the submucosal component. Emergent visceral angiography may be diagnostic if 1) a characteristic arteriovenous malformation is identified, and 2) extravasation of contrast into the bowel lumen indicating active bleeding is demonstrated. Angiograms may also demonstrate small bowel lesions which cannot be reached by endoscopy.

Our criteria for diagnosis of angiomata as the bleeding site in a patient with clinically severe upper or lower GI bleeding are: 1) active bleeding from the angioma, 2) an affixed clot, 3) nearby clots and no other GI lesions present to account for the bleeding, or 4) extravasation of contrast material on an angiogram and, on endoscopy, a non-bleeding angioma in that bowel segment. Repeat elective panendoscopy may be necessary at times to diagnose UGI angiomata that may be obscured by blood or clots. Oral lavage preparation for elective or emergent colonoscopy is useful to cleanse the colon of stool, clots, and blood. Diagnostic and therapeutic endoscopies or colonoscopies may be performed on outpatients with intravenous sedation, provided the patients are medically stable.

Coagulation of angiomata via endoscopy or colonoscopy is feasible with several different thermal

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devices: argon laser, YAG laser, monopolar electrocoagulation, bipolar electrocoagulation (BICAP), and heater probe. Following endoscopic coagulation, ulcers form in the coagulated zone but tend to heal and re-epithelialize with normal mucosa or scar tissue. Healing of UGI coagulated sites may be facilitated by antiulcer medication.

EQUIPMENT

For diagnosis of bleeding colonic angiomata, a thin caliber (12-13mm) single-channel colonoscope with a large (3.7mm) suction channel is useful. This instrument can be used for treatment also with laser catheters, BICAP, heater probe or monopolar electrocoagulation.

For diagnosis and treatment of bleeding UGI angiomata, useful instruments include a therapeutic endoscope (single large suction channel or double channel), a thin caliber panendoscope (such as an Olympus OES XQ-10) and a duodenoscope with a standard sized channel (2.8mm), all of which allow passage of small (2.4mm) coagulation probes or laser catheters.

The choice of coagulation units for angiomata depends upon the experience, training, and skill of the endoscopist and funds available. The relative cost of the equipment (machine and accessories) for endoscopic YAG or argon lasers is 10 to 20 times higher than for BICAP, heater probe or monopolar electrocoagulation. The end result — coagulation efficacy — is similar for all thermal units in well-trained hands. For contact probes, small (2.4mm diameter) ones are useful for small angiomata treatment and large probes (3.3mm) facilitate coagulation of larger angiomata. Both sized probes should be available for physicians using the heater probe or BICAP for GI angiomata coagulation.

INDICATIONS AND CONTRAINDICATIONS

The goals of endoscopic treatment are coagulation of the angioma, re-epithelialization with more normal mucosa and, thereby, cessation of the GI bleeding. Because the pathogenesis of these lesions is unknown and recurrences are common over time, cure is rarely achieved unless underlying medical conditions can be cured.

Patients with documented bleeding from GI angiomata often benefit from endoscopic coagulation. In our referral population with bleeding, 95% of patients with documented UGI angiomata bleeding and 80% with colonic angiomata had improved outcomes after endoscopic coagulation. Because successful palliation depends upon healing of induced ulcers, patients who are likely to heal their ulcers and who will live at least 60 days should be selected.

Contraindications to GI angiomata coagulation via endoscopy include a contraindication to initial or repeat endoscopy. A significantly abnormal and uncorrectable coagulopathy will often cause the patients to have delayed hemorrhage from induced ulcers secondary to coagulation of angiomata. Patients with short life expectancies (less than 60 days), because of underlying medical conditions, often do not benefit from endoscopic coagulation and palliation. Instead, these patients should usually be treated just with supportive care.

Patients with vey extensive angiomata (such as in OWR syndrome covering more than 25% of the stomach) or numerous angiomata (covering more than 50% of the right colon) should be considered for palliative surgery rather than endoscopic palliation.

Truly incidental angiomata (i.e., not associated with bleeding) should not be coagulated. Prophylactic treatment is not indicated unless future studies document a benefit of such treatment.

UTILIZATION

The prevalence of bleeding GI angiomata is unknown in the United States. However, in our referral hospitals (i.e., UCLA and Wadsworth VA Hospital), bleeding UGI angiomata account for 6-9% of severe UGI bleeding and colonic angiomata for 30% of patients with severe lower GI bleeding. These patients have severe bleeding requiring hospitalization and intensive care unit management. Approximately 67% of patients referred with GI angiomata have less severe GI bleeding and are referred as outpatients for endoscopic treatment. Endoscopic coagulation is feasible at the bedside through the same instruments used for endoscopic diagnosis. This is particularly true for portable instruments (BICAP, heater probe, monopolar electrocoagulation) rather than laser which often requires movement of the patient to a laser unit. Approximately 90% of all angioma patients are amenable to endoscopic coagulation; 10% are not because of a contraindication, usually related to a severe underlying disease. For the patients treated by the CURE Hemostasis Research Group, 95% of UGI and 80% of LGI angiomata patients have benefited from endoscopic palliation over mean follow-up periods of 2 years (UGI) and 1.5 years (LGI), respectively. The complication rates compared with surgical resection are low.

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RESULTS OF ENDOSCOPIC THERAPY

Successful palliation was possible in about 80% of our colonic angiomata cases with severe lower GI bleeding and over 95% of UGI angiomata cases with documented angiomata bleeding. In patients with severe bleeding and "incidental angiomata" (not meeting criteria defined above for the bleeding site), no patient (0 of 14) had successful palliation of their bleeding with endoscopic coagulation with argon laser, BICAP or heater probe. During the follow-up of the latter patients, 70% were eventually found to have other, non-angiomatous, bleeding sites; 30% continue to have recurrent GI bleeding but a diagnosis has not been possible in spite of very extensive evaluations.

PALLIATIVE RESULTS — UGI ANGIOMATA

In terms of palliation after endoscopic coagulation, refer to TABLE 1 for CURE Hemostasis Research Group's patients. Patient outcomes were compared for equal periods of time before and after endoscopic coagulation.

TABLE 1. UGI ANGIOMATA — PALLIATION RESULTS

Time from Endoscopic Coagulation	2 Years Before	2 Years After
Number of Patients		
OWR	21	21
Non-OWR	48	48
Mean Number of GI Bleeds		
OWR	5.2	2.2
Non-OWR	3.7	1.4
Mean Units RBC Transfused		
OWR	19.3	7.8
Non-OWR	10.7	4.5

For both groups (OWR and non-OWR), there was a significant decrease in the number of GI bleeds and units of blood transfused after endoscopic coagulation compared with before treatment. There were no differences among the coagulation devices in these overall outcomes. However, for the OWR patients, argon laser was easier and less time was required for a coagulation session than with the contact devices (BICAP and heater probe). With argon laser, lesions could be treated from a distance and contact was not required as was necessary with heater probe or BICAP. Most of our OWR patients had at least a hundred telangiectasia and required several coagulation sessions. For these OWR patients, approximately one-third the treatment time was required for argon laser vs. the contact probes. Nevertheless, contact probes are effective, and with a deliberate and persistent approach, hemostasis and good palliation can be achieved with BICAP and heater probe. For non-OWR patients with UGI angiomata, treatments with heater probe, BICAP or argon laser were equally efficacious and safe. Non-OWR angiomata patients tended to have fewer lesions (mean: 5) to coagulate than OWR patients (mean: 100).

PALLIATIVE RESULTS — COLONIC ANGIOMATA

Overall, 80% of patients had their bleeding controlled with endoscopic coagulation. Fifty-five percent (55%) had no further bleeding after 1 colonoscopic coagulation session. Twenty percent (20%) required two or more colonoscopic sessions. Six percent (6%) required a UGI coagulation subsequently for UGI bleeding angioma.

Sixteen percent (16%) of the patients required surgery for severe rebleeding. Six percent (6%) had poor palliative results from surgery or colonoscopic coagulation. The overall palliative results are shown in TABLE 2. Each patient's course after colonoscopic coagulation is compared with the same number of months before treatment.

TABLE 2. PALLIATIVE RESULTS — COAGULATION OF COLONIC ANGIOMA

	2 Years Before	2 Years After	P Value
Number of Patients	55	55	
Mean Hct	27	36	<0.05
Mean Bleeding Episodes	5	1	<0.05

Factors associated with severe rebleeding during the follow-up period included incomplete initial colonoscopy (usually because of poor prep), failure of the patient to return for follow-up after hemoccults became positive, multiple or large angiomata on initial colonoscopy, severe heart or renal failure, and an abnormal bleeding time. These factors were prognosticators independent of the kind of coagulation modality used.

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COMPLICATIONS

There were no complications of urgent purge. However, some patients on dialysis for chronic renal failure retained significant fluid and were therefore dialyzed just after purge to avoid severe fluid overload.

Post-coagulation syndrome (localized abdominal tenderness without findings of free perforation) was diagnosed in one patient after heater probe coagulation and one after BICAP coagulation in the right colon. Both were treated medically. Both had multiple, right colonic, large angiomata all treated during a single treatment session.

Colonic ulcerations after treatment were common. Severe delayed bleeding (3-7 days after coagulation) was seen in two patients with abnormal bleeding times (1 each with BICAP and heater probe). Both patients required surgery for hemostasis. Post-coagulation syndrome, delayed bleeding or any other complication was not seen in any patient treated with argon laser coagulation.

RESULTS AND COMPLICATIONS OF OTHERS

Excellent short term (6 months) palliation of bleeding angiomata patients without complications has been reported with endoscopic argon laser. Good short term palliation was also reported for YAG laser coagulation of GI angiomata but the complication rate, 10-20%, is substantially higher than with argon laser, heater probe and BICAP, particularly for colonic lesion. Reported complications after YAG coagulation of angiomata include delayed hemorrhage, deep ulceration and delayed healing, perforation and pneumoperitoneum.

Successful and safe palliation of colonic angiomata has been reported with hot biopsy forceps, a form of monopolar electrocoagulation. Others, however, report a high frequency of complications with this device and do not consider it safe enough to recommend widespread clinical use.

COST ANALYSIS AND BENEFIT

There are no prospective cost analyses data reported for bleeding GI angiomata. However, we have estimated the cost of hospitalizations and blood transfusions for our angiomata patients. These data are shown in TABLE 3 for the OWR, UGI non-OWR, and colonic angiomata patients treated by the CURE Hemostasis Research Group.

The costs are estimated only based upon index prices of $150 per unit of blood transfused and mean hospitalization of four days with each bleeding episode at $500 per day, or $2,000 per hospitalization. The cost analysis does not include cost estimates for diagnostic tests, ICU admission, blood work or routine laboratory tests. All these would substantially increase the cost of routine care for bleeding angiomata patients before, compared to after, endosopic coagulation. Nor are the costs of non-endoscopic care (surgery, medications, angiography) or endoscopic hemostasis included.

TABLE 3. ESTIMATED HOSPITALIZATION AND TRANSFUSION COSTS BLEEDING ANGIOMATA PATIENTS

Time Relative to Coagulation	**Before**	**After**
Mean Years		
OWR	2 years	2 years
UGI Non-OWR	2 years	2 years
Colonic	1.5 years	1.5 years
Number of Patients		
OWR	21	21
UGI Non-OWR	48	48
Colonic	55	55
Mean Hospitalization Cost		
OWR	$10,400	$4,400
UGI Non-OWR	$ 7,400	$2,800
Colonic	$10,000	$2,000
Mean Transfusion Cost		
OWR	$ 2,895	$1,170
UGI Non-OWR	$ 1,605	$ 675
Colonic	$ 3,150	$ 600

In spite of the limitations of this cost analysis, there was at least a two-fold reduction in the cost for transfusions and hospitalizations for the mean F/U period of 1.5 - 2 years. Even if the cost of endoscopic hemostasis is added to the post-randomization costs ($800 for simultaneous diagnostic and therapeutic endoscopy), the costs of care are significantly reduced.

Provided that the complication rates remain low (2% in our series with heater probe, BICAP, or argon laser), palliative endoscopic management of carefully selected patients offers great promise over conventional management. Whether one considers rebleeding frequency, hospitalizations, transfusions, or cost of care, there are advantages of endoscopic hemostasis for bleeding angiomata. At this time, there are no data to support the medical or cost benefit of coagulation of incidental angiomata.

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Sclerotherapy of Esophageal Varices

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INTRODUCTION

Esophageal varices are dilated veins that develop in the esophagus in certain diseases, mainly cirrhosis of the liver, that are associated with increased pressure in the portal venous system. When the flow of portal blood through the liver is compromised, portal blood pressure rises and compensatory pathways develop to accommodate varying proportions of blood from the gastrointestinal tract. The most clinically significant component of this collateral vascular system is the esophageal varices with their propensity to bleed.

Although it would seem that some method of preventive treatment could eliminate or reduce the potential for variceal hemorrhage in patients who have not yet bled, all methods of therapy carry an appreciable immediate complication rate, mortality and potential for long term side effects. The prognosis for patients with variceal hemorrhage depends mainly on the severity of their underlying disease. With advanced liver disease, the mortality is 40% during the first six weeks after onset of bleeding.[1]

There are several temporary methods for immediate control of variceal bleeding, including drug therapy and balloon tamponade. A logical approach to bleeding from esophageal varices would be to permanently divert the blood in the blocked portal system to the general body circulation. This can be done by surgically creating a portasystemic shunt. The major obstacle to shunt surgery, however, is that substantial quantities of blood are diverted from the liver. As a result, many toxic substances absorbed from the gastrointestinal tract are not metabolized before they reach the general body circulation and cause encephalopathy. Any potential merits of emergency shunt surgery are now moot since there are data that demonstrate that sclerotherapy of esophageal varices is more cost-effective.

The only promising approach to long-term control of variceal bleeding until the resurgence of sclerotherapy has been shunt surgery[2]. Recent trials demonstrate a decrease in bleeding, an increase in encephalopathy, and no marked survival advantage for operated patients[3,4]. Certain drugs have been employed to decrease blood flow and pressure in the portal venous system on a long-term basis[5,6]. Data on the outcome of this therapy are conflicting. Some well-controlled trials have not demonstrated any value for this treatment[6].

PROCEDURE DESCRIPTION AND EQUIPMENT

Elimination of varices from within the esophagus using an endoscope would, in theory, prevent hemorrhage. For technical reasons based on variceal anatomy, the injection of a chemical substance is currently the most practical endoscopic approach. The concept of the injection method is that a chemical reaction within or near a varix will result in inflammation, clot formation within the varix, and eventually collapse and obliteration of the vessel.

All endoscopes have a channel within the long flexible portion of the instrument that is inserted into the patient. Through this channel instruments such as an injection needle for sclerotherapy may be passed into the lumen of the gastrointestinal tract. Special endoscopes for treatment of gastrointestinal bleeding usually have a channel with a larger diameter, or two channels, so that blood and clots can be suctioned even when a device to control bleeding has been introduced through the channel. Special therapeutic endoscopes usually have additional features such as the capability to flush water or other fluids into the field of view to wash away clots and debris, as well as control mechanisms within the instrument to direct various hemostatic devices introduced through the instrument channel.

Most sclerotherapy procedures can be performed after intravenous administration of moderate doses of sedative drugs. General anesthesia is not necessary, and the patient thus remains conscious, although sedated, during the procedure.

Special injection devices can be introduced through the channel of the endoscope to inject one or more chemical agents ("sclerosants") into the varices. Such a device usually consists of a simple needle at the end of a long flexible tube of small diameter. A variety of chemical substances has been used for sclerotherapy. Whether any one agent is superior with respect to effectiveness and potential complications is uncertain.

During sclerotherapy, the endoscope is positioned in the lower part of the esophagus, a site on one of the varices is selected by direct observation, and the needle of the injection device is thrust into or adjacent to a varix. The needle is maintained in position for about 10 to 30 seconds during which time the chemical agent(s) is injected, usually with the assistance of a nurse who operates the syringe. Several injections are made in a pattern designed to inject all of the major variceal vessels. The actual number of injections, concentration of the sclerosant(s), volume of sclerosant injected, and the overall pattern of injections varies according to the technique of the physician endoscopist. A single sclerotherapy procedure may control active bleeding, but a series of 4-6 such procedures are usually needed to completely eradicate the varices and reduce the chance of recurrent bleeding. There is uncertainty as to the course of events once the varices are obliterated. It is thought by some experts that new varices may arise in the course of time. Therefore, some endoscopists continue to perform endoscopy at intervals to assess the progress of the patient once the varices have been initially obliterated.

INDICATIONS AND CONTRAINDICATIONS

Sclerotherapy is indicated for control of active variceal hemorrhage and for prevention of recurrent bleeding. Sclerotherapy may be useful for prevention of bleeding in patients with varices who have not had bleeding, but data pertaining to such prophylactic treatment are limited. Variceal hemorrhage may be active at the time a patient presents for treatment, in which case the most immediate clinical problem is to stop the bleeding. One tactical approach with ongoing bleeding is to use simple treatment methods initially, such as intravenous drugs. This may be done as an attempt to temporarily stabilize the patient's condition in anticipation of subsequent sclerotherapy. Variceal hemorrhage persists in some patients despite the basic measures of intravenous drugs, transfusion and perhaps tamponade. In such cases, sclerotherapy may be performed as an emergency measure to stop bleeding. Some endoscopists do not routinely employ the standard measures for control of bleeding. Rather, they consider sclerotherapy to be the primary method for stopping active variceal bleeding, and begin sclerotherapy as soon as possible without resorting to other therapeutic measures.

Variceal hemorrhage in a patient with severe end-stage liver disease presents a vastly different array of complex clinical problems than a similar degree of variceal bleeding in a patient with well-preserved liver function. In the former case, the prognosis is worse and there are few treatment options that do not carry a significant and frequently prohibitive risk. The condition of these patients often precludes shunt surgery, and therefore sclerotherapy becomes the procedure of choice.

Patients with good liver function who have survived an episode of variceal hemorrhage and have entered a relatively stable period may be candidates for shunt surgery. However, there are usually no contraindications to a protracted course of sclerotherapy in such patients. Unfortunately, there are only a few clinical trials in which surgery has been compared to sclerotherapy in "good risk" patients, so that there are relatively little data and information available to guide the choice of therapy.

RESULTS OF SCLEROTHERAPY

Sclerotherapy is thought to control acute variceal bleeding in at least 75% of episodes[8-22]. In nearly all of these series, tamponade and/or intravenous drugs were used to stabilize patients prior to sclerotherapy. However, in a series from Fleig, et al[23], hemorrhage was controlled in 92% of patients unresponsive to balloon tamponade. Another report by Barsoum et al[24] is of interest in this respect. Fifty patients were treated by tamponade and 50 by sclerotherapy. Sclerotherapy was successful in 74%, and tamponade alone in 42% of patients.

An important trial of sclerotherapy in 36 patients compared to medical management in 28 control patients was published in 1980[11]. In this investigation, Clark et al found that bleeding recurred in one-third of sclerotherapy patients versus two-thirds of control patients. The study of Clark was extended in a report by MacDougall et al[25]. The most remarkable aspect of this report was that survival at one year was better for sclerotherapy-treated patients (75% versus 58% for patients who received "medical" management), this difference being statistically significant. A third report from this group of investigators[26] included 56 patients treated by sclerotherapy and 60 control patients. The median follow-up was 37 months with a range of 19 to 68 months. Mortality in the sclerotherapy group was 18% versus 32% for the control group (statistically significant). Death due to bleeding occurred in 5% of the sclerotherapy patients versus 25% of the control ("medically" treated) patients (highly significant statistically). Survival as determined by cumulative life analysis was significantly better in the sclerotherapy group. In addition, there was a significant and favorable difference with respect to the total number of episodes of hemorrhage for those undergoing sclerotherapy. Others have also indicated a favorable effect on survival[10,27-29].

Since the results of sclerotherapy have been good in patients who have had variceal hemorrhage, there is considerable interest in the possibility of performing sclerotherapy in patients with varices who have not yet sustained an episode of bleeding. Witzel et al[30] reported a 25-month long trial of prophylatic sclerotherapy. Patients in the sclerotherapy (56 patients) and control (53 patients) groups were evenly matched with respect to age, sex, and cause of liver disease. Variceal bleeding occurred in five sclerotherapy patients (9% versus 30 control patients (57%), a statistically significant difference. The overall mortality rates for the sclerotherapy patients and untreated patients were 21% and 55% respectively, also a statistically significant difference. Death as a result of variceal hemorrhage occurred in two sclerotherapy patients (4%) versus ten control patients (18%) (statistically significant). Paquet et al[31] have reported on several controlled trials of prophylatic sclerotherapy. In the first randomized series of patients reported by these authors, the

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incidence of variceal bleeding in patients not undergoing sclerotherapy was 66% and mortality 42%[11]. The incidence of bleeding in patients treated by sclerotherapy was 6% with a mortality of 6%, a statistically significant difference.

Cello et al[12] have reported a trial of sclerotherapy versus portacaval shunt surgery in 52 patients with severe cirrhosis, each of whom had received at least six blood transfusions because of acute variceal hemorrhage. Twenty-eight patients received sclerotherapy and 24 underwent operation. A significantly greater number of patients had recurrent bleeding in the sclerotherapy group compared to those undergoing operation, although the total volume of blood transfused was greater in the surgical patients. Survival at 30 days was about 40% in both groups. With respect to long term outcome, a significantly greater number of patients were rehospitalized for recurrent bleeding in the sclerotherapy group, and the total number of days spent in the hospital for bleeding was also significantly greater. However, total number of blood transfusions, the number of patients rehospitalized for encephalopathy, total days in hospital for encephalopathy, and the resumption of alcohol abuse did not differ between the two groups. On the basis of this trial in patients with acute variceal hemorrhage, the authors concluded that sclerotherapy and emergency shunt surgery were equally effective.

The preliminary results of a prospective, randomized trial of sclerotherapy and a special type of surgical shunt procedure known as a distal splenorenal shunt have recently been reported by Warren et al[13]. Patients were stratified within each of the two treatment groups according to severity of liver disease. There were 36 patients in the sclerotherapy group and 35 in the operated group. Nineteen of 36 (53%) sclerotherapy patients had recurrent bleeding versus one of 35 shunted patients (3%) (statistically significant). However, recurrent bleeding was controlled in all but 11 (31%) of the 36 sclerotherapy patients by repeated injection sessions. Those patients in whom sclerotherapy failed to control bleeding underwent surgery. Median follow-up was 26 months. At two years, there was a significant improvement in survival in the sclerotherapy group (including patients who underwent sclerotherapy and surgery), which was 84%, versus survival in the shunted group, this being 59%. There was also some evidence that liver function was better maintained or even improved in those patients in whom sclerotherapy was successful.

COMPLICATION RATE

The complication rate for sclerotherapy ranges from 2% to 15% per patient[8,11-13,14-15]. A reasonable estimate of the complication rate per patient when sclerotherapy is performed by an expert would be about 10%. Many complications of sclerotherapy are considered minor and not life-threatening. Serious complications occur in less than 10% of patients and include serious bleeding, perforation, mediastinitis, esophageal ulcers or strictures, portal vein thrombosis, fistulas, and pulmonary emboli.

COST ANALYSIS

Chung and Lewis[16] reported an analysis of the cost of management of patients with bleeding esophageal varices by four different treatment methods. Group 1 consisted of six patients who underwent shunt surgery. This was performed on an emergency basis in two cases and as an elective procedure in four patients who were not actively bleeding. Group 2 included 24 patients who received only supportive ("medical") treatment. Group 3 consisted of seven patients who underwent emergency surgical ligation of esophageal varices after supportive medical treatment failed to control bleeding. Ligation of variceal vessels at surgery consists merely in tying sutures around the major variceal vessels. It is a less extensive operation that is more suited to patients with severe liver disease. It is also less effective in the control of bleeding than shunt surgery. Group 4 included nine patients who underwent emergency sclerotherapy and three patients who were treated by sclerotherapy on an elective basis after bleeding had stopped. The overall clinical status of the patients was not evenly matched for each of the groups. Patients in poor condition were not considered for surgery and therefore the sclerotherapy and "medical" treatment groups (Groups 2 and 4) included more patients with advance liver disease. The bias in this study was therefore in favor of Groups 1 and 3 in which surgery was the main form of therapy. The total cost of treatment per patient in each group and the cost per survivor at two years were determined. This investigation was performed between 1977 and 1979 so that the dollar amounts do not take inflation into account.

In the study of Chung and Lewis[16] the approximate professional fees in 1978 dollars for surgical shunt (Group 1), surgical ligation (Group 3), and sclerotherapy (Group 4) were respectively $1,300, $1,100 and $250. The treatment costs included charges for hospital services, such as laboratory, radiologic and other diagnostic tests, medications, blood and blood products, and physician fees were assessed.

The length of hospital stay was longest in Group 3, and shortest in Group 4. The incidence of recurrent variceal bleeding was about the same for the four groups, and this was the most common reason for rehospitalization after initial treatment. The

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sclerotherapy-treated group of patients had the fewest number of readmissions to the hospital. Follow-up elective procedures in the sclerotherapy treatment program were performed on an outpatient basis which resulted in considerable cost savings. The cost of each outpatient sclerotherapy session, including physician fees, endoscopy room charges, and clinical fees, was approximately $410 (1978 dollars).

There was no significant difference in survival at two years' follow-up for any of the groups. The overall cost of shunt surgery for the six patients in Group 1 was $88,200. The cost of treatment per surviving patient in Group 1 was $44,200. The total cost of care for the 24 patients in the "medical" supportive treatment group (Group 2) was $258,100 with the cost per two year survivor being $23,400. The overall cost for the treatment of the seven patients (Group 3) who underwent surgical ligation of varices was $157,900 with the cost per two year survivor being $52,700. The cost of sclerotherapy treatment of the 12 patients in Group 4 totalled $98,400 with the cost per two year survivor being $12,300. Sclerotherapy thus proved to be the most cost-effective method of management despite the bias of including sicker patients in this treatment group.

The results of the investigation of Cello et al[12] in which sclerotherapy compared favorably to shunt surgery in the emergency treatment of variceal hemorrhage in patients with severe liver disease are outlined above. In this report published in 1984, the total health care costs per patient were significantly greater for patients undergoing surgery ($23,957 ± $3,111) than for those treated by sclerotherapy ($15,365 ± $2,200).

There are considerable cost savings when sclerotherapy can be performed on an outpatient basis. In the report of Drell et al[17], the average cost for an inpatient sclerotherapy procedure was $1,183 while that for an outpatient session was $339.

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Endoscopic Treatment Of Strictures Of The Gastrointestinal Tract

Gastric Balloon Dilation

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INTRODUCTION

Chronic gastric outlet obstruction in the audit population is most frequently caused by peptic ulcer disease, particularly of the pylorus. Postoperative causes include narrow surgical repairs or anastomotic edema and fibrosis in patients undergoing gastroenterostomy for ulcer disease or gastric surgery for morbid obesity. Common symptoms include post-prandial fullness or pain, weight loss, nausea and vomiting. Traditional surgical treatment for gastric outlet obstruction has consisted of a vagotomy plus pyloroplasty or antrectomy for pyloric stenosis, and revision of an anastomosis or staple line in postoperative stenosis. While usually successful, postsurgical morbidity ranges between 10-13% and includes problems of weight loss, post-vagotomy stasis and diarrhea, and the dumping syndrome. Balloon dilation of gastric stenoses has been developed in an attempt to correct symptomatic gastric outlet obstruction without surgical intervention, thus obviating the above complications and avoiding the morbidity and mortality of the surgery as well.

EQUIPMENT

Hydrostatic balloons for use in the stomach are currently available from a number of manufacturers. Catheters are generally 7mm in diameter and 150-180 cm in length. Balloon sizes range between 8-20 mm and can either be placed over a 300 cm long guide wire or directly through an endoscope. A pressure gauge is required to measure pressure generated within the stricture, and fluoroscopy is used to detect balloon inflation as a correlate of adequate stenosis dilation.

PROCEDURE AND DESCRIPTION

Most gastric stenoses have been dilated using hydrostatic balloons passed over an endoscopically-positioned guide wire. After premedication with local pharyngeal anesthesia and intravenous sedation, the stomach and stenosis are visualized with a small diameter endoscope and residual gastric fluid is aspirated. A guide wire is then placed through the endoscope and passed through the strictured area into the duodenum as ascertained radiographically. The endoscope is withdrawn and a balloon that approximates the endoscope size is placed over the guide wire and passed into the stricture. The balloon is inflated using an equal mixture of water and contrast agent until stricture dilation is noted fluoroscopically. Generally, this requires pressures of 30-40 psi for up to 60 seconds. This sequence can then be repeated with larger balloons either at the same time or several weeks later. If the recently developed, through-the-scope balloons are used, the catheters are placed through the endoscope into the strictured area without the need for a guide wire. Fluoroscopy is still required to ascertain adequate stricture dilation.

Depending upon the clinical setting, patients may have to be hospitalized after the procedure to rule out a complication. When the stricture was due to acid-peptic disease, patients usually require short-term treatment with a prokinetic agent, such as metoclopramide to enhance stomach emptying, and long term therapy with acid-reducing drugs (cimetidine, ranitidine, etc.)

INDICATIONS AND CONTRAINDICATIONS

Indications for hydrostatic dilation of gastric and pyloroduodenal strictures can be divided into acid-peptic, postoperative, and miscellaneous stenoses. Most benign ulcers that cause gastric outlet obstruction are in the pyloric channel. Less commonly, distal antral and proximal duodenal bulb ulcers can obstruct the stomach. Patients who should be considered for balloon dilation as opposed to conventional surgery include those who refuse surgery, the older patient (greater than age 60) who has increased surgical morbidity and mortality, or the patient of any age whose surgical risk is excessive due to associated disease.

Patients who have an extremely small opening after gastric bypass stapling or bypass surgery will develop postprandial pain, nausea and vomiting and previously have required surgical revision. The majority of such patients should now undergo an attempt at endoscopic dilation therapy first. Patients who develop acute post-operative outlet obstruction of a gastroenterostomy should be treated with nasogastric suction for several weeks. If the anastomosis still has not opened, most should undergo hydrostatic dilation prior to an additional surgical operation.

Miscellaneous gastric stenoses that can be treated with hydrostatic balloons include antral Crohn's disease and, occasionally, gastric neoplasms.

Contraindications to balloon dilation include, in addition to the usual contraindications to upper GI endoscopy, an active deep ulceration, an uncooperative patient, and an inability to adequately ascertain balloon position fluoroscopically.

UTILIZATION

Peptic ulcer disease is a common affliction in the United States with an incidence of 1-2 per 1,000 individuals and a prevelance between 5-10%. Ap-

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proximately 10% of ulcer patients will develop complications such as bleeding, perforation, or obstruction, and many will require surgical intervention. It has been estimated that approximately 2,000 patients per year require surgery for obstruction. The percentage of anastomotic stenoses following stomach bypass or stapling for morbid obesity has been reported to be between 0-30%, with most series approximating 5%. Early postoperative stenosis following gastroenterostomy occurs in about 1% of cases, and late stenosis occurs in some who develop recurrent ulceration.

RESULTS OF ENDOSCOPIC THERAPY

Although there have been anecdotal reports and small series reporting efficacy in patients undergoing balloon dilation for gastric stenoses, there have been no large series reported to date. In a recent survey sent to 3000 members of ASGE, 248 of 1538 responding endoscopists were using balloon dilation in the GI tract. Two hundred (200) of these 248 were using balloon dilation in the stomach and had performed a total of 545 gastric dilations. Technical success rates for passing the balloon into the stenosis and inflating it ranged from 76% in pyloric to 87% in postoperative stenoses. Symptomatic relief of obstructive symptoms were reported to be 67% at 3 months or beyond. Radiographic visualization was checked in a subset of patients and showed 60% improvement acutely in those checked. The long term efficacy rates remain undefined and repeat or sequential dilations may be necessary.

Side effects for gastric balloon dilation include those of standard endoscopy (drug reaction, aspiration, vasovagal reaction) as well as bleeding and perforation (0.9%).

COST ANALYSIS

Comparing costs should take into consideration not only the initial costs but also the need for a repeat endoscopic or surgical procedure on the one hand versus loss of work and recuperative time following major surgery on the other. However, procedural and hospitalization costs are more readily available and compare as follows for a large community hospital in the Northwest:

Surgery (vagatomy and pyloroplasty; CPT Code 43640)	
Surgical fee	$ 2,324
Anesthesia fee (3 hours)	700
Average operating room charge	1,226
Average recovery room charge	72
Standard room and hospital charges	11,900
TOTAL COST	**$16,222**

Endoscopy	
Endoscopy fee	$ 600
Accessory fee (endo, cart, nursing time drugs, supplies)	150
Recovery room	50
X-ray suite	70
One day hospitalization (Optional)	(350)
TOTAL COST	**$ 870**
with hospitalization	($1,200)

SUMMARY

While it is yet uncertain which patient with acid-peptic induced pyloric stenosis should undergo balloon dilation as opposed to surgery, most patients with stenotic gastroenterostomy or gastric stapling/bypass surgeries deserve an initial trial of endoscopic dilation. The risk of acute side effects of hydrostatic dilation is acceptable and total costs appear to be 1/10 to 1/20 of those of conventional surgery. Long term efficacy/patency rates remain to be defined.

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Endoscopic Treatment Of Strictures Of The Gastrointestinal Tract

Treatment Of Esophageal Stenosis

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INTRODUCTION

Dysphagia, or difficulty swallowing, may result from intrinsic or extrinsic obliteration of the esophageal lumen or neuromuscular disorders of the pharynx and esophagus. Non-surgical methods for relieving esophageal obstruction due to strictures are primarily those of peroral dilation and indwelling peroral esophageal prosthesis. As a general principle, compression of the esophagus from without is not responsive to peroral dilation, whereas intramural lesions secondary to scarring or neoplasm usually respond, depending upon the type of obstruction. About 15% of patients with malignant obstruction require placement of a peroral prosthesis for relief from dysphagia.

PROCEDURE DESCRIPTION

Peroral esophageal dilation ordinarily is performed on an outpatient basis, usually using pharyngeal anesthesia by gargle and minimal or no sedative-analgesic preparation (Demerol and Valium), depending upon the individual patient's tolerance and the complexity of the dilation technique.

The procedure is most simply and safely performed with the patient lying on the fluoroscopy table. The entire procedure is usually controlled under fluoroscopic guidance. Esophageal dilators, with or without a previously passed guide wire are passed by mouth through the area of stenosis in a sequential fashion. A good practice is not to pass more than three dilators per sitting that meet moderate or greater resistance. The goal of most dilations is to ultimately achieve a lumen size of at least 15 mm diameter in order to give the patient reasonably complete relief from solid food dysphagia. The passage of each dilator usually requires less than 10 seconds. The frequency of dilation is determined by the patient's response, the duration and the etiology of the stricture. Strictures secondary to long-standing chemical injury of the esophagus generally are more resistant and risky to dilate and as a consequence the dilation scheduling should be at a more gradual pace. Malignant strictures will require more regular dilation to maintain adequate lumen patency than benign strictures. Most patients are kept under surveillance after optimum lumen size is achieved and at a minimum they should be evaluated by the physician at least on an annual basis to determine the need for further therapy.

EQUIPMENT

The necessary equipment for routine stricture dilation is a complete set of mercury-filled rubber bougies of the Maloney or Hurst type and a complete set of metal (Eder-Puestow) or hard plastic (Savary) dilators used over a guide wire. These latter instruments are most valuable for very stenotic or irregular strictures, particularly those associated with diverticula, ulceration or acute lumen angulation. In a few patients, a fiberoptic esophagoscope is necessary to pass a guide wire through an eccentric strictured lumen; the wire is then guided by fluoroscopy into the proper position. Through-the-scope (TTS) hydrostatic dilator balloons made of an inelastic plastic polymer are helpful in some cases to accomplish the initial dilation of complex strictures.

Accessories include a suction apparatus with a disposable aspiration cannula, extra stainless steel guide wires, pressure gauges for hydrostatic and pneumatic dilators and thin angiographic guide wires to be used in some as lumen finders.

Peroral esophageal prostheses and introduction apparatus are available commercially and also may be made easily using polyvinyl tubing. About half of the patients who require a prosthesis will need one that is of special size or form for best results; therefore, the operator should be able to fashion the polyvinyl tubing.

INDICATIONS AND CONTRAINDICATIONS

Mucosal or intramural lesions resulting in either a benign or malignant stenosis of the esophagus represent the usual indications for peroral esophageal dilation. Virtually all esophageal strictures are amenable to peroral dilation. Patients with malignant obstruction who have failed to respond to dilation and radiation therapy are candidates for an esophageal prosthesis.

INDICATIONS

A. Peroral Dilation
    1. Benign esophageal strictures due to reflux, chemical agents (corrosives), radiation and post-surgical anastomotic strictures
    2. Malignant strictures due to cancer of the esophagus or proximal stomach

B. Peroral Prostheses
    1. Malignant obstruction not responsive to dilation
    2. To occlude an esophago-pulmonary fistula

Treatment Of Esophageal Stenosis

H. WORTH BOYCE, JR., M.D.

CONTRAINDICATIONS

1. Patients who are extremely ill with concomitant disease or in a preterminal state.
2. Patients with coagulopathy, severe thoracic aortic aneurysms or complicated strictures not suitable for guide wire placement and safe passage of the dilation instrument.

UTILIZATION

It has been estimated that somewhere between 5% and 10% of patients with symptomatic gastroesophageal reflux disease will have or develop an esophageal stricture. Since reflux disease is extremely common in our population, reflux-related strictures make up the largest volume of patients who will be in need of peroral esophageal dilations. In many gastroenterology centers, peroral esophageal dilation is performed as frequently and in some, more often than any other gastrointestinal procedure.

Since the majority of the 10,000 patients who are diagnosed each year with esophageal cancer are not reasonable candidates for surgical therapy, esophageal dilation or prosthesis placement will be required at some time during the remainder of their lives following diagnosis of this condition.

RESULTS OF DILATION THERAPY

It has been estimated that moderate to good results are obtained in over 80% of patients with benign esophageal strictures and an equal number of patients with malignant strictures. Obviously, those with benign strictures are far more likely to obtain complete relief of symptoms than are those with malignant strictures, for whom dilation is simply a temporary help. At least 60% of patients undergoing dilation for benign esophageal strictures will require repeat dilations in the future. With each repeat dilation, the chance of the patient requiring an additional dilation increases significantly. On the other hand, approximately 40% of patients with benign strictures require only a single dilation session for permanent relief.

Patients with esophageal cancer have been shown to be palliated, with temporary relief of dysphagia in about 90% of cases. Obviously, because of the nature of the carcinoma, stenosis tends to recur and either repeated dilations, laser therapy, or ultimately an indwelling esophageal prosthesis are required. The long-term survival in patients with malignant esophageal obstruction does not appear to be increased; however, the improved quality of life, with restored ability to swallow saliva and a modified diet, is considered adequate palliation.

The major complication of peroral esophageal dilation is perforation of the pharynx or esophagus. The perforation risk varies with different types of dilation procedures. The ASGE survey in 1976 revealed the following perforation risks for the various types of dilators: Mercury-filled — 4/1000 patients; metal olives — 6/1000 patients. Dilation of malignant strictures and placement of a peroral prosthesis using proper technique with fluoroscopic control and gradual dilation is associated with perforation rates under 2.0%. Significant bleeding after dilation is a rare event, as is symptomatic bacteremia. Transient bacteremia occurs commonly, but in all but the immunocompromised patient, is of no consequence. In patients with high risk from bacteremia, antibiotic prophylaxis is generally recommended.

Although in more complicated strictures repeat dilation sessions are necessary, peroral dilation remains by all considerations a far superior technique to thoracotomy and operation on the esophagus for benign strictures and esophageal cancer. Experience over the past twenty years has shown that peroral dilation is extremely effective and safe and is preferred in virtually all cases of benign and most of those with malignant stenosis. Thoracotomy and esophageal resection for cancer of the esophagus is the highest risk elective procedure performed in the world today, an overall mortality between 5% and 30%. Mortality of less than 5% is reported from a few highly specialized centers where large numbers of patients are operated upon for esophageal cancer.

COST ANALYSIS AND COMPARATIVE COST-BENEFIT vs. PERORAL DILATION AND PROSTHESIS

Surgery		
Routine Hospital Days = 8 (1 pre-op; 7 post-ICU)	at $246/day	= $1,968
Day of Operation:		
OR Fee	$1,540	= $5,160
Recovery Room	570	
Surgeon (Prof. fee)	2,300	
Anesthesiologist (Prof. fee)	750	
ICU days = 3	at $492/day	= $1,476
Medication/Miscellaneous Costs		$1,300
TOTAL		**$9,904**

Endoscopic Treatment Of Strictures Of The Gastrointestinal Tract

Treatment Of Esophageal Stenosis

H. WORTH BOYCE, JR., M.D.

Peroral Dilation		
No Hospitalization required for over 90% of cases.		
Room Charge (room, fluoro, meds)		$ 150
Prof. Fee		$ 120
TOTAL		**$ 270**
Estimate 4 dilations for each patient followed for 12 months with severe stricture would be:		
4 x 270 TOTAL		$1,080
Peroral Esophageal Prosthesis		
Routine Hospital Days = 5	at $246/day	= $1,230
Day of Procedure:		
Endoscopy Room Charge	$ 200	
Fluoroscopy	25	
Preparatory Dilation	150	$1,035
Esophagoscopy	210	
Prosthesis Co[illegible]	150	
Prosthesis (Prof. Fee)	300	
Medication/Miscellaneous Costs		= $ 15
TOTAL		**$2,280**

Comparable costs are difficult to calculate because 60% of patients with benign esophageal stictures require repeated dilations. On the average however, most patients with severe strictures over the first two or three years of therapy will not require more than four to six dilation treatments. If we calculate the cost for patients who ultimately have strictures that respond to dilation and compare that with surgery cost we have some idea of the relative cost-effectiveness. Hospitalization for esophagectomy for benign strictures usually will require approximately 10 days. Since many of the patients with cancer are quite emaciated and malnourished, they may require several weeks of central-venous nutrition prior to operation. If this is necessary, the hospital costs would be much higher.

Peroral dilation, however, is usually performed on an outpatient basis with local anesthesia. The entire peroral dilation procedure can usually be completed within 10 to 15 minutes under fluoroscopic control; the patient is discharged after a brief period of observation, can return to normal activity and can resume meals as soon as he or she has recovered from pharyngeal anesthsia.

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Endoscopic Treatment Of Gastrointestinal Polyps And Cancer

Colonoscopic Polypectomy

JEROME D. WAYE, M.D.

INTRODUCTION

Cancer of the colon and rectum is the second most common cancer in the United States. This cancer begins in colon polyps and develops through progessive stages of cellular transformation, resulting in malignant degeneration of a previously benign colon or rectal polyp. There are several types of polyps, but adenomas are the only ones that degenerate into cancer. The factors that tend to be associated with a higher incidence of malignancy are the size of the polyp and the amount of villous component (assuming a fibrillar or cauliflower-like appearance). Colon polyps do not usually give rise to symptoms, and are most frequently discovered because of the passage of blood mixed in with the stool during defecation, or may be discovered by testing the stool for occult blood (not visible to the naked eye).

Currently available evidence suggests that removal of polyps will prevent the subsequent development of colon and rectal cancer. Utilizing a colonoscope to remove polyps permits performance of the procedure in most instances as an outpatient at greatly reduced cost. When surgery is used to remove polyps, hospitalization of 7 to 10 days is required and the individual is lost to the work force for 4 to 6 weeks.

PROCEDURE DESCRIPTION

A long flexible instrument is passed under direct vision through the entire colon by a trained endoscopist. When a polyp is seen, a snare device is passed through the endoscope and a wire loop is placed around the polyp base or stalk. The polyp is severed from its attachment to the colon wall by passing an electrocautery current through the wire loop, resulting in separation without blood loss. A total colonoscopic examination is recommended whenever one polyp is discovered since others are found in approximately 35-50% of patients. Polyps may resemble warts, with a flat base growing on the colon wall (sessile) or may resemble a cherry on a stem (pedunculated polyp). Large polyps attached with a broad-base may require several applications of the snare to safely shave the growth off the colon wall. Polyps attached by a stem or pedicle can frequently be removed with one current application. All polyps transected should be recovered and sent to the pathology laboratory for microscopic analysis seeking the specific category for that particular growth as well as the presence or absence of cancer if the polyp proves to be an adeoma. Small polyps in the colon can be removed with a technique of biopsy and fulguration utilizing a single instrument, the "hot biopsy forceps", which provides a histologic sample while electrocoagulation current destroys the residual polypoid tissue.

The procedure of colonoscopy may be somewhat uncomfortable and usually requires the use of intravenously administered sedatives. A trained gastrointestinal assistant is necessary to assist the endoscopist as well as to observe the patient at all times during the examination.

EQUIPMENT

The colon is a non-sterile organ filled with bacteria. Long flexible colonoscopes, approximately 6 feet in length, enable the examiner to visualize the entire length of the convoluted human large intestine. Visual images and light transmission are usually provided through fiberoptic technology. More recently, video-endoscopes with an electronic "chip" on the tip of the instrument have been developed which hold great promise as a tool for the future. Whichever instrument is utilized, disinfection of the instrument and its working channels is necessary following each intubation of the colon. The newer model instruments permit total immersion, facilitating disinfection.

A snare is a device which actually removes the polyp from its attachment to the colon wall. A wire loop contained within an insulated plastic sheath may be extended into a lasso which encircles the polyp. Electrocautery current passed through the snare results in cautery of the polyp's blood vessels so that bleeding is unusual once the poly is removed. An electrosurgical unit is a separate external device to generate the type of current needed for electrocautery. A few snares should be available for each endoscopic procedure in case of malfunction. Hot biopsy forcept may be required for the removal of small polyps; this device can obtain a specimen of tissue as well as cauterizing its base to destroy any residual polypoid tissue. At present, almost any well-defined polyp can be successfully removed from the colon with available endoscopic techniques.

INDICATIONS AND CONTRAINDICATIONS FOR THE PROCEDURE

A polyp is any elevated growth within the intestinal tract. This definition covers many different histologic types of polyps, and those that require removal are adenomas, which are the ones considered at risk for subsequent degeneration into colon cancer. Unfortunately, it is usually not possible to determine which polyps are adenomas until they have been removed and sent to the pathologist for microscopic identification. Therefore, the presence of a polyp within the colon requires that it be removed. Contraindications to removal of colon polyps include: moderate or severe blood coagulopathy, poor general medical condition of the patient, inability to adequately visualize the polyp with the colonoscope, and those cases where endoscopic access is not possible. Special risks occur in patients with cardiac pacemakers and those prone to develop an infection induced by colonoscopy such as patients with valvular heart disease, prosthetic cardiac valves, and other artificial implants.

UTILIZATION

It is estimated that approximately one-third of the general population have or will develop colonic adenomas. Approximately 5% of these adenomas will become malignant. The incidence of malignancy in adenomas is approximately 1% of those 1 cm in diameter (approximately ½ inch), and rises with the increasing size of the adenoma. Because of the association between colon adenomas and the subsequent development of colon cancer, treatment directed only at surgical resection of colon cancers ignores the pre-cancerous lesion, the colon polyp. It is considered that removal of colon polyps will markedly decrease the incidence of colon cancer in any population.

RESULTS OF ENDOSCOPIC THERAPY

The desired result is the eradication of colon polyps and disruption of the adenoma-carcinoma sequence. Endoscopic removal of adenomas can be safely performed in the vast majority of patients. Once a polyp on a stem has been removed by transection of the stalk, the polyp is 100% removed and will not recur. The patient is cured of that polyp. Approximately 35-50% of patients have other adenomas in the colon, which must be sought and also removed. When flat polyps are shaved off from the wall, it may not be possible to ensure their complete removal, and follow-up endoscopic examinations will be necessary to inspect the site and if necessary to remove further residual polypoid tissue. Once an adenoma is removed, it is necessary to repeat the colonoscopic examination at regular intervals for surveillance purposes, since that colon has a high chance of developing more lesions. The growth rate of colonic adenomas is rather slow, taking perhaps 5 or more years to reach a size that places the patient at risk for cancer developing within the polyp.

COMPLICATIONS OF COLONOSCOPIC POLYPECTOMY

In general, the risks from sedative medications are low and are the same as with diagnostic colonoscopy. Bleeding may follow transection of the polyp due to inadequate coagulation of the nutrient blood vessels, either because of the large size of the vessel or because of inadequate application of coagulation current. Hemorrhage may be immediate, and if severe, requires either blood transfusions or a surgical operation for control. Late bleeding may begin approximately one week following polypectomy, when the "scab" on the cauterized vessel falls off. Moderate or severe bleeding occurs in 1-2% of cases. Perforation (puncture through the wall) occurs in about 0.3% of cases and is an indication for immediate surgical repair of the colon.

COST ANALYSIS

Except for very large polyps or in rare, high risk cases, colonoscopic polypectomy has replaced surgical resection of polyps at laparotomy. The cost savings provided by colonoscopic polypectomy, which is usually performed as an outpatient procedure, is substantial as demonstrated by the following simple comparison utilizing charges from a midwestern university hospital:

	Colonoscopic Polypectomy	**Surgical Polypectomy**
Length of stay	Outpatient 1-2 days	7 days
Physician fees		
Endoscopist	$ 600	——
Surgeon	——	$1,250
Anesthesiologist	——	$ 480
Total physician charge	$ 600	$1,730
Hospital charges		
Room	——	$2,400
Lab (clinical)	$ 100	$ 430
Operating room	——	$1,600
Endoscopy room	$ 250	——
Recovery room	$ 40	$ 125
SICU	——	$ 700
Drugs	$ 30	$ 120
Medical supplies	$ 16	$ 485
Total hospital charges	$ 436	$5,860
Total physician and hospital charges	**$1,036**	**$7,590**

Endoscopic Treatment Of Gastrointestinal Polyps And Cancer

Colonoscopic Polypectomy

JEROME D. WAYE, M.D.

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Esophageal Cancer: Laser Treatment

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INTRODUCTION

Esophageal cancer is a devastating disease. In addition to the physical and mental burdens which may attend any cancer, it interferes with the basic necessity and pleasure of food ingestion. Because symptoms usually do not begin until the disease is far advanced and because there is no practical screening test for asymptomatic persons, cure is almost never possible and most treatment is palliative. Endoscopic laser therapy (ELT) is a new treatment method which can be used for palliation for esophageal cancer.

PROCEDURE DESCRIPTION

The most common symptom of esophageal cancer, dysphagia, is usually caused by luminal obstruction by the tumor. Relief of the obstruction generally improves swallowing. The endoscope can be advanced to the neoplasm and a laser waveguide can be inserted through a biopsy channel in the endoscope. The guide exits through the distal tip of the endoscope and it can be aimed at the malignant tissue under direct vision. The laser beam heats the tissue, causing thermal destruction. The size and geometry of esophageal cancers is such that serial sessions (mean = 3; range: one to five) are usually required to relieve obstruction.

The procedure is performed using topical pharyngeal anesthesia and intravenous sedation (e.g., meperidine and diazepam). General anesthesia is not utilized. In addition to the endoscopist, two other health personnel are present — one to care for the patient and one to monitor the laser and assist the physician. The laser treatment session lasts 60 to 90 minutes. If subsequent sessions are required, they are generally performed at 48-hour intervals.

EQUIPMENT

Necessary equipment includes the laser, a waveguide, the endoscope, and some accessory equipment. A variety of commercially marketed lasers are available in the United States. The neodymium:yttrium aluminum garnet (Nd:YAG) laser with a power output of 90-100 watts is generally employed. This new technology has only become available in the last decade.

The waveguide is the major advance that has allowed laser technology to be coupled with flexible endoscopes. This thin, flexible strand of quartz or glass is the delivery system that carries the beam from the laser via the endoscope to the treatment site. Developments are proceeding with waveguides to maximize their utility. Alteration of the tip may allow the energy intensity, beam direction, and other characteristics to be varied.

Conventional endoscopes can be used but several different types may be required depending on the nature of the esophageal lesion. The endoscopes are often modified for the safety of the patient (e.g., gas exhaust), the endoscopist (e.g., filter for eye protection), and the scope itself (e.g., construction of tip to minimize damage from heat, light, and debris).

Accessories which are generally available in a standard endoscopic unit (biopsy forceps, dilators, water pumps, polyp graspers) may be used.

INDICATIONS AND CONTRAINDICATIONS

The goals of palliation for the patient with esophageal cancer are: 1) to provide adequate nutrition in as normal a way as possible, 2) to assist in the maintenance of a normal lifestyle, 3) to control pain and maintain comfort, and 4) to retard tumor growth. Several other modes of palliation (surgery, radiation therapy, chemotherapy, dilatation, endoscopic prosthesis placement, gastrostomy/jejunostomy) have been utilized to achieve these goals. In most patients, a combination of therapies is applied. Endoscopic laser therapy has been used to open the esophageal lumen so that goals (1) and (2) can be achieved. It is unclear at this time as to where ELT should fit into the therapeutic sequence and which patients are best suited for ELT and which for other forms of treatment. It is currently employed primarily in patients whose tumor is no longer responsive to radiation and chemotherapy and is inoperable.

INDICATIONS

1) Palliative relief of dysphagia and bleeding caused by esophageal cancer.
2) Part of a curative treatment regimen for esophageal cancer in the rare patient with localized disease who is not a candidate for more conventional curative therapy (e.g., surgery, radiation therapy).

CONTRAINDICATIONS

1) Routine contraindication to endoscopic therapy
2) Endoscopic access to esophageal cancer not possible

UTILIZATION

Approximately 10,000 cases of esophageal cancer are discovered in the United States each year. Since cure will be possible in less than 5%, palliative treatment will be required in most instances. By far the most common symptom for which treatment is employed is dysphagia. In the large majority of patients with esophageal cancer, therefore, ELT will be a therapeutic option.

RESULTS OF ENDOSCOPIC THERAPY

Since ELT for esophageal cancer was first reported in 1982, more than 2,000 patients have been treated in the United States, Europe and Japan. A great deal of data are available regarding initial outcome but data about long-term outcome are difficult to interpret. In greater than 90% of patients who are treated with ELT for esophageal obstruction, luminal patency (technical success) can be achieved. However, in some of these patients, because of anorexia, dysmotility, painful metastatic disease, or complications of therapy, adequate nutrition cannot be maintained despite the technical success of the treatment. Overall functional success occurs in approximately 70% of patients.

It is difficult to assess the effect of ELT on long-term survival in a meaningful way. To date, most patients have received ELT as a "last resort". Laser therapy is often selected in terminal patients who have failed other modalities. Additionally, the role of ELT is only to relieve obstructive symptoms and reduce dysphagia. Since it does not have a role in tumor retardation, the overall outcome will be more apt to be influenced by rapidity of tumor growth. In one retrospective study, ELT was shown to improve survival.

The major complication associated with ELT has been perforation. The overall incidence has been 5-8%. Transient bacteremia occurs but sepsis has not been a problem. Minor complications that resolve without treatment include pain during and after treatment and gaseous overdistention. The incidence of these complications is approximately 10%. The overall mortality associated with the treatment per se is less than 1%.

When assessing the safety and efficacy of any treatment, its merit in relation to alternative therapeutic options must be weighed. ELT has some unique advantages and disadvantages. It differs from surgery in that it does not require general anesthesia. Surgery, however, is generally completed with one procedure, whereas serial sessions are required with ELT. It differs from radiation therapy (RT) and chemotherapy (CT) in several important ways. Its results are more immediate. Benefit from RT and CT may take weeks to achieve. Additionally, since ELT is performed under direct vision and involves local treatment, systemic side effects are unlikely. Finally, if tumor recurs after ELT, retreatment can be carried out. There is no maximal dose of treatment as is the case with RT. By definition, ELT is limited and does not have the ability to arrest tumor growth outside the esophagus like CT or RT.

A comparison of the complication rates of ELT and surgery for esophageal cancer is listed below.

	ELT	**SURGERY**
Mortality	1%	10-25%
Perforation	5-8%	3%*

*anastomotic leak

COST ANALYSIS AND BENEFIT

COMPARATIVE COSTS: SURGERY VS. LASER PALLIATIVE TREATMENT ESOPHAGEAL CANCER

Surgery		
Routine Hospital Days = 8 (1 pre-op; 7 post-SICU)	@$ 385	$ 3,080
Day of Operation		$ 6,720
OR Fee	1,920	
Recovery Room	300	
Surgeon (Prof. fee)	3,000	
Anesth. (Prof. fee)	1,500	
SICU Days = 3	@ $ 970	$ 2,910
	TOTAL	**$12,710**
Laser		
Routine Hospital Days = 6	@ $ 385	$ 2,310
Laser Treatment: = 3 Days	@ 830	$ 2,490
Room Charge	330	
Professional Fee	500	
	TOTAL	**$ 4,800**

The above information is based on actual figures from a University Medical Center on the East Coast. It is projected that a patient who undergoes a palliative resection for esophageal cancer will be hospitalized 11 days. Hospitalization prior to surgery is standard. Operating room fee is figured on a time of 4 hours which is average with a recovery room time of 3 hours. The professional fees are means within a wide range. Three intensive care days are usual.

The laser costs assume three treatment sessions, which is the mean number required, and it assumes that [illegible] of the treatments are done as in-patients. It assumes that each procedure lasts 1½ hours. The professional charge of $500 is often assessed.

It can be seen that endoscopic laser therapy for palliative treatment of esophageal cancer costs considerably less than palliative surgical resection. If laser treatment accomplishes the same goals and the duration of benefit is similar, it is a better choice than surgery. A study comparing these two procedures would be extremely important.

Esophageal Cancer: Laser Treatment

DAVID E. FLEISCHER, M.D.

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Endoscopic Treatment Of Gastrointestinal Polyps And Cancer

Endoscopic Laser Treatment Of Colon Cancer

MARK H. MELLOW, M.D.

INTRODUCTION

Colorectal cancer is one of the most common cancers affecting Americans today. The primary treatment is surgical, and surgical treatment is based upon several sound principles, including 1) complete removal of all malignant tissue, 2) prevention and/or cessation of bleeding, 3) prevention and/or relief of obstruction, 4) "debulking" of primary tumor load. Unfortunately, a sizeable minority of patients with colorectal cancer are elderly, debilitated, or have serious underlying medical conditions. In addition, many patients with rectal cancer require extensive surgery (removal of the rectum — that is, abdomino-perineal resection, with performance of a colostomy). Because of the attendant risks of surgery in the patient types delineated above, and the desire of many patients to avoid colostomy, alternatives to surgery are desirable. Finally, many patients have advanced disease at the time of initial diagnosis, and therefore, surgery is purely palliative and life span is short (5-10 months). Endoscopic laser therapy is a new treatment method which may be utilized in selected patients with colorectal cancer. Successful laser treatment can accomplish the goals of palliative surgery, i.e., prevention and/or cessation of bleeding; prevention and/or relief of obstruction; and debulking of the primary tumor mass — without the attendant surgical morbidity and mortality.

PROCEDURE DESCRIPTION

For treatment of colorectal cancer, the endoscope is inserted into the rectum and advanced to the area of the neoplasm. A laser waveguide is then passed through the biopsy channel of the endoscope, exiting through the distal tip of the scope where it can be aimed directly at the malignant tissue under direct vision. Laser energy delivered to the target neoplasm causes tissue destruction by thermal energy. Usually, several sessions (mean = 2.5; range 1-5) are required to produce the desired effect. There are two potential "desired effects". By far the most common one is palliation in a patient with known widespread disease. In this instance, sufficient malignant tissue is destroyed to provide an opening adequate for the passage of gas and feces. In rare patients in whom the tumor is small and localized, complete destruction of the tumor can be accomplished with resultant cure. The procedure is performed in a manner similar to routine diagnostic colonoscopic examinations. By far the most common lesions currently being treated with the laser are in the rectum or rectosigmoid. In such cases, pre-procedure preparation with one or two cleansing enemas is all that is necessary. For treatment of more proximal colonic lesions, full cleansing preparation must be employed as would be used for colonoscopy. The procedure is performed after intravenous sedation (e.g., meperidine and diazepam). General anesthesia is not required. In addition to the endoscopist, there are generally two other health personnel present — one to care for the patient and one to monitor the laser and assist the physician. The laser treatment session usually lasts 30-60 minutes. The initial group of treatment sessions is performed at approximately 48-hour intervals, until the desired effect is achieved. Patients then require follow-up visits every 4-8 weeks depending upon the original intraluminal mass and regrowth characteristics of the tumor, and the general condition of the patient. Again, the aim of palliation is to maintain a patent lumen sufficient for the passage of gas and fecal matter as well as photocoagulation of tumor surface bleeding. In the occasional patient in whom endoscopic cure is the goal, following destruction of all visible malignancy, multiple biopsies are obtained at the base of the treated area. Endoscopic follow-up with multiple biopsies in the area of previous tumor is then performed at least every 3 months for the first year following treatment.

EQUIPMENT

Equipment used in endoscopic laser therapy includes the laser, a waveguide, the endoscope and some accessory equipment. A variety of commercially marketed lasers are available in the United States. The neodymium yttrium aluminum garnet (neodymium-YAG) laser with a power output of 90-100 watts is most commonly employed. This new technology has become available during the last decade. The development of the waveguide is the major advance that has allowed laser technology to be coupled with flexible endoscopes. This thin flexible strand of quartz or glass is the delivery system that carries the beam from the laser via the endoscope to the treatment site. Developments are proceeding with waveguides to maximize their utility. Alteration of the tip may allow the energy intensity, beam direction and other characteristics to be varied. Conventional endoscopes can be used for laser treatment. For lesions in the rectum, an upper endoscope is often used primarily because one does not need the extra length of scope to reach the target site and time is saved, as the laser fiber is frequently passed in and out of the biopsy channel of the endoscope in order to clean the tip and allow suctioning. Accessories which are generally available in a standard endoscopic unit (e.g., biopsy

Endoscopic Laser Treatment Of Colon Cancer

MARK H. MELLOW, M.D.

forceps, dilators, electrocautery snares, polyp graspers) may be used. Thin suction catheters may also be inserted into the rectum adjacent to the scope to suction out air introduced into the colon by the laser fiber itself. One of the persons assisting the physician during the laser endoscopy will be in charge of frequently assessing the patient's abdomen for undue distension. Should that be found, the laser fiber is removed from the scope, and suction is applied through both the scope and the thin suction catheter.

INDICATIONS AND CONTRAINDICATIONS

The indications for endoscopic laser therapy of colorectal cancers include relief and/or prevention of obstruction; relief and/or cessation of hemorrhage, and primary "debulking" of tumor mass in patients with colorectal cancer who are not surgical candidates because of advanced age or severe coexisting medical conditions. Additionally, laser therapy might be considered preferable to standard surgical therapy in selected patients with known far advanced disease at time of diagnosis and in some patients who refuse surgical therapy. It must be emphasized that lesions in the rectum are far more appropriate for laser treatment than lesions in the more proximal colon. The reasons for this include 1) accessibility (preparation requires only cleansing enemas, and advancement of the endoscope to the tumor target is easy), 2) low chance of disastrous complications (perforation of the rectum below the peritoneal reflection will not result in free abdominal perforation and peritonitis), 3) less appealing treatment alternatives (need for abdominoperineal resection with colostomy, versus anterior resection and primary closure for lesions in the colon). Finally, there will be some instances in which endoscopic laser treatment can be used for curative purposes. In this category are selected patients with large villous adenomas, and those clinically localized malignant diseases (after performing appropriate tests to exclude extrarectal spread). Endoscopic laser therapy can also be used in combination with other oncologic therapy such as radiation or chemotherapy.

CONTRAINDICATIONS

Laser treatment is contraindicated in most patients with lesions amenable to surgical "cure" who are not unduly high surgical risks.

UTILIZATION

Colorectal cancer is one of the most common internal malignancies in the United States for men and women combined. It will occur in approximately 5% of U.S.-born men and 6% of women. Approximately 50% of patients with colorectal cancer may be cured with surgical resection. Unfortunately, approximately 30% have advanced disease at the time of diagnosis. In addition, many patients are elderly and have significant associated medical conditions, raising the mortality and morbidity of surgery. The effect of age on operative mortality for A-P resections for rectal cancer is striking, ranging from approximately 2.5% in patients up to age 60 to over 15% in patients over age 70. In addition, morbidity is substantial, with a significant number of urinary tract, cardiovascular, pulmonary, septic, bowel obstructive, and colostomy complications being reported. Thus an appreciable number of patients with colorectal cancer will either be not surgically treatable for cure or will be at high risk for surgery. The exact proportion of these patients who should undergo alternative treatment such as endoscopic laser therapy is unknown at the present time, since randomized studies involving these treatments have not been performed.

RESULTS OF ENDOSCOPIC THERAPY

The use of endoscopic laser therapy for colorectal cancers is, like that of all other endoscopic laser techniques, in its relative infancy. The bulk of the world's experience has come from two French investigators. There are no studies available that compare in a randomized, controlled fashion results of endoscopic laser therapy for colorectal cancer to those of surgery or electrofulguration. In addition, there are very few long-term data available. Approximately 1000 patients have been treated worldwide, the vast majority having rectal cancers. As stated previously, laser treatment has been used for relief and/or prevention of obstruction, relief and/or cessation of bleeding, and the need or wish to avoid surgery. In almost all patients with rectal cancer, these initial goals can be accomplished. However, treatments must be repeated, usually every 4-8 weeks. If one defines an unsuccessful course of therapy as one which ends in the need for an operation based upon inability of laser treatment to maintain an adequate lumen, or need for an operation because of patient dissatisfaction with the technique, "unsuccessful" laser therapy is seen in 5-15% of patients. While a few investigators have reported survival data, it is difficult, in the absence of a randomized study, to compare results to surgery with any certainty. Median survival in patients with far advanced disease treated by endoscopic laser therapy has been 7-10 months. This is quite similar to the data reported for far advanced colorectal cancer in general. The major complication associated with endoscopic laser therapy has been per-

Endoscopic Treatment Of Gastrointestinal Polyps And Cancer

Endoscopic Laser Treatment Of Colon Cancer

MARK H. MELLOW, M.D.

foration, in 3-10% of cases. Pain after treatment is usually transient and hardly ever requires more than the use of a non-narcotic analgesic. Gaseous overdistension occurs but is less of a problem than seen in laser treatment of esophageal cancers. Anal stenosis occurs in 2-5% of cases and usually responds to dilatation. Perirectal abcesses have been reported in 2-3% of patients. The overall mortality associated with laser treatment per se is less than 1%. When comparing the safety and efficacy of laser treatment for colorectal cancer to that of surgical management, one must bear in mind the type of operation needed and the age and medical condition of the patient. While surgical morbidity and mortality is higher than that of laser therapy, especially for lesions requiring AP resection, surgical therapy is generally completed in one procedure, whereas serial sessions are required for laser therapy. Laser treatment may get more difficult as time passes. Therefore, patients who are at low risk for surgery and whose stage of cancer is such that a life expectancy of greater than 18-24 months is expected, would best be treated surgically. On the other hand, elderly patients with significant associated medical conditions who require AP resection and/or who have far advanced disease at the time of diagnosis, might benefit more from endoscopic therapy.

There are no data comparing the use of laser therapy for rectal carcinoma to that of electrocauterization. Based upon published data, electrocauterization appears to be associated with higher morbidity and greater cost, as procedures are performed in the operating room under general anesthesia, and post-procedure recuperation is longer than with laser therapy. However, electrocautery might be favored in certain patients with intramural rectal lesions being treated with curative intent.

COST ANALYSIS AND BENEFIT

The following data represent actual mean values of patient costs from a review of patients treated for rectal and rectosigmoid cancer at a private University-affiliated hospital in the Southwestern United States over the previous 12 months. Three sets of charges are presented:

1) abdomino-perineal resection, 2) laser treatment — in-patient, 3) laser treatment — out-patient. The laser costs assume three treatment sessions, which is the mean number required for initial treatment of rectal cancer. Approximately 60% of the initial laser treatments and virtually all follow-up laser treatments were performed as out-patient procedures. (TABLE 1)

Since, unlike abdomino-perineal resection for rectal cancer, follow-up laser treatments are required, the following represents figures for costs of follow-up laser treatment in the 12 months after initial therapy:

Total cost for a follow-up out-patient laser treatment = $908; performed on an average of every 7 weeks, = $908 x 7 = $6,356 in one year. Presuming median survival of 12 months in patients with far advanced rectal cancer, total lifetime cost for outpatient laser treatment would be less than half that of abdomino-perineal resection. (Note that re-operations are sometimes required in patients who have undergone AP resections. These costs are not addressed in this analysis.)

TABLE 1

	AP Resection	***Laser Therapy** (In-Patient)	***Laser Therapy** (Out-Patient)
Length of Stay	17 days	5 days	—
Physician Fee			
Surgeon	$ 2,267	—	—
Anesthesiologist	500	—	—
Gastroenterologist	—	$1,350	$1,350
Hospital Charges			
Hospital Room	2,590	925	—
Intensive Care Unit	1,650	—	—
Operating Room	1,183	—	—
Recovery Room	119	—	—
Endoscopy Use	—	330	330
Laser Use Fee	—	700	700
Others (Pharmacy, Medical-Surgical Supplies, Anesthesia, Etc.)	11,458	1,378	80
Total	**$19,767**	**$4,683**	**$2,460**

*Three Laser Treatment Sessions

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Endoscopic Treatment Of Disease Of The Biliary Tract

Biliary Stent Placement

JEROME H. SIEGEL, M.D.

INTRODUCTION

The use of biliary endoprostheses for palliative decompression of obstructive jaundice is a relatively new technique for the treatment of obstructive diseases of the biliary tree.

In general, carcinoma of the pancreas is usually not a resectable lesion and therefore is rarely curable. A similar dismal outlook applies to malignant tumors of the bile duct. For this reason, nonsurgical palliative methods for treating obstructive disease of the biliary tree are desirable.

PROCEDURE DESCRIPTION

We have incorporated an algorithm into the work-up and evaluation of patients presenting with cholestasis or obstructive jaundice. Expeditious diagnosis and therapy for these conditions is desirable. Ideally, patients should be evaluated the day of admission after undergoing preliminary screening and diagnostic tests as outpatients. Once obstructive disease is suspected, the patient undergoes an endoscopic procedure using a fiberoptic instrument which is designed to effectively visualize the second portion of the duodenum where the openings of the bile duct and pancreatic duct are located. Both the bile duct and pancreatic duct empty their contents through a papilla or nipple called the ampulla of Vater, into the duodenum. Once the endoscope is introduced into the patient's mouth, it is advanced through the esophagus and into the stomach where the entrance to the duodenum is identified and negotiated. Once in the duodenum, the ampulla of Vater is identified. The endoscope contains a channel through which accessories can be advanced. The biliary tract examination usually begins with insertion of a cannula or catheter which is passed into the bile duct. Contrast material is injected through the cannula to localize by x-ray the site of obstruction. Once the site of obstruction is confirmed, the catheter is removed and a sphincterotome, a special accessory which can create an incision, is inserted into the ampulla. An incision or sphincterotomy is not always necessary but is helpful in introducing some of the other accessories into the bile duct. Once the sphincterotomy is accomplished, a catheter containing a guide wire is introduced through the sphincterotomy to negotiate the stricture and is advanced into the proximal biliary tree above the stricture. The catheter is then removed from the guide wire, and a special prosthesis of a desired diameter and length is advanced over the wire through the endoscope and then out of the endoscope into the bile duct, traversing the stricture. The optimal location of this prosthesis should be as follows: 1) the more distal end of the prosthesis is placed above the obstruction, i.e., in the proximal bile duct or liver where it will collect bile and provide a conduit through which bile can flow to the duodenum, and 2) the more proximal end of the prosthesis is located in the duodenum.

The procedure is performed using topical spray to the throat and intravenous analgesia. The procedure rarely takes more than one hour to complete.

The success rate for the procedure is about 90%, and the mean hospital stay is 4 days.

EQUIPMENT

The equipment necessary to complete this procedure includes the endoscope and its accessories. The endoscope is either a standard endoscope used for this purpose or is a larger-channel endoscope which allows passage of a prosthesis of greater diameter. In addition to the light source, an electrocautery generator is required to create an incision. Catheters and guide wires are necessary for injection of contrast and insertion of prostheses. Prostheses kits containing accessory catheters, guide wires and prostheses are commercially available at a reasonable price. A sphincterotome is necessary to perform the incisional sphincterotomy.

INDICATIONS AND CONTRAINDICATIONS

This procedure is indicated in the treatment of obstructive jaundice due to the following: 1) cancers of the pancreas, 2) periampullary carcinomas, 3) primary bile duct tumors, and 4) metastatic disease to the extrahepatic biliary tree. Occasionally, endoprostheses are used to treat benign biliary strictures, to facilitate healing of fistulas and to maintain bile flow when common duct stones are not amenable to either surgical or endoscopic therapy.

Palliative treatment of obstructive jaundice which decompresses the biliary system is recommended to re-establish bile flow and restore digestion of essential nutrients. Bile in the gastrointestinal tract improves the general well-being of patients, as well as improving their appetite and nutritional status. Relieving biliary obstruction also reduces bile salt deposition in the skin which causes itching that can be severe and debilitating. Alternative therapy to endoscopic decompression includes surgery or percutaneous insertion of prostheses (passing through the skin and liver to the bile duct).

Indications

Palliation of obstructive jaundice and relief of symptoms associated with this entity.

Contraindications

Routine contraindications to endoscopic therapy.

Endoscopic Treatment Of Disease Of The Biliary Tract

Biliary Stent Placement

JEROME H. SIEGEL, M.D.

UTILIZATION IN CANCER OF THE PANCREAS

It is estimated that more than 26,000 cases of cancer of the pancreas occur annually in the United States. Fewer than 10% of these lesions are resectable. Despite all therapeutic efforts, fewer than 0.4% of patients survive two years after diagnosis. Since cure is usually not possible, alternative therapy for palliation is desirable. In addition to patients with cancer of the pancreas, palliation is also necessary for patients presenting with primary and metastatic tumors of the bile duct causing obstructive jaundice. This latter inclusion increases the annual total of treatable patients by 4,000 to 5,000.

RESULTS OF ENDOSCOPIC THERAPY

The endoscopic approach to the management of obstructive jaundice has been successful in approximately 90% of the cases in which it has been attempted. The procedure is usually accomplished in one day, and requires another day or two of observation and antibiotic therapy to prevent infection of the prosthesis or biliary tree. The mean hospital stay for these patients is less than 4 days, as opposed to the surgical approach, which may require up to 21 days. Percutaneous drainage procedures are accomplished after one or two sessions and require five to six days of hospitalization. The large caliber endoscopic prostheses are effective for up to 6 months, whereas the percutaneous catheters usually require more frequent replacement.

The endoscopic method, therefore, requires shorter hospital stays when compared to both surgical and other non-surgical techniques. The general well-being of the patient improved immediately after insertion of a prosthesis, and there are no surgical wounds or scars requiring additional medical attention. Since the endoscopic biliary prosthesis is internal, it requires no external abdominal or thoracic incision or accessory. These qualities make the endoscopic procedure most acceptable. Large caliber prostheses remain patent and effective for as long as 6 months. Since the mean survival of patients with carcinoma of the pancreas is less than 4 months, the prosthesis will generally outlast the patient in whom it was placed. The quality of life through this period is better preserved, since the patient has not been subjected to a surgical procedure. The major complications associated with the insertion of biliary endoprotheses are those associated with the most invasive part of the endoscopic procedure, sphincterotomy. Perforation of the bowel wall, pancreatitis and/or bleeding occur in less than 3% of patients in whom this procedure is performed. Transient fever following insertion of the prosthesis occurs in another 8-10% of patients; however, this figure is less than 2% in patients in whom a large caliber prosthesis has been placed, or in patients who have been maintained on antibiotics. Complications requiring surgical intervention are rare. Mortality following the endoscopic procedure is less than 1%, whereas the overall mortality following surgery approaches 20%.

COST ANALYSIS AND BENEFITS

Comparative cost; Surgery vs. endoscopic decompression in the palliative treatment of obstructive jaundice.

Surgery	
O.R. Fee	$ 2,000
Recovery Room	300
Surgeon Fee	4,000
Anesthesiologist	1,500
Intensive Care (3 days @ $800)	2,400
Routine Hospital Days (12 days @ $425)	5,100
Other Costs (Drugs, monitors, consultants)	3,000
TOTAL	**$18,300**

Endoscopic Decompression	
Endoscopy (x-ray)	$ 300
Room charge	
Routine Hospital Days (3 days @ $425)	1,275
Professional Fee	1,500
Miscellaneous (Drugs, IV's, etc.)	400
TOTAL	**$ 3,475**

Difference between endoscopic therapy and surgery: **$14,825.**

The above information is based on actual figures from a survey of medical centers in the New York City area. In general, palliative bypass surgical procedure requires at least 15 days in the hospital. However, a more definitive radical resection for cancer usually requires 21 to 28 days. Since the endoscopic procedure is palliative, figures for palliative bypass surgery are compared, i.e., 15 days, total cost $18,300, compared to 3 days for the endoscopic procedure, total cost $3,475. The difference, therefore, between endoscopic therapy and surgical palliation is $14,825. If we exclude regional differences for cost, an annual savings of 312,390 patient days can be attributed to the endoscopic treatment of cancer of the pancreas.

Studies indicate that recurrent problems following surgery occur in approximately 25% of patients requiring repeat hospitalization during the survival period of the patient. The rehospitalization frequency for exchange of biliary endoprostheses is no more than one hospital visit usually, since patients with cancer of the pancreas do not usually survive more than 6 months.

Endoscopic Treatment Of Disease Of The Biliary Tract

Biliary Stent Placement

JEROME H. SIEGEL, M.D.

Unless new methods are developed which allow cure of cancer of the pancreas or other neoplasms which obstruct the biliary tree, the treatment of choice appears to be nonsurgical endoscopic palliation. Fewer than 10% of patients evaluated for malignancies of the pancreas and bile duct should undergo surgical resection. This 10% includes patients in whom nonsurgical procedures fail.

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Endoscopic Treatment Of Disease Of The Biliary Tract

Endoscopic Retrograde Sphincterotomy (ERS)

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INTRODUCTION

Extrahepatic biliary obstruction is a common problem. A frequent cause of this problem is stones in the common bile duct which can usually be treated with ERS.

PROCEDURE DESCRIPTION

This procedure is done by passing a special cannula called a papillotome through an endoscope into the common bile duct. The papillotome has an exposed wire attached to the tip which protrudes 20-30mm from the end of the cannula. This wire can be bowed against the sphincter of Oddi by manipulating an external handle. The sphincter of Oddi consists of circular bands of muscle tissue in or near the ampulla of Vater at the terminal end of the biliary duct. After it has been placed in proper position, electrical current is applied to the wire to cut through the sphincter fibers. The purpose of the procedure is to open the distal bile duct and allow the removal of stones. It is also used for very distal strictures of the sphincter called papillary stenoses which may be true stenoses or defects in the muscle. The procedure has been used to cut through tumors of the ampulla of Vater to allow biliary drainage. Spincterotomy may also be used to enlarge the orifice of the common bile duct to allow passage of a stent through strictures or tumors.

EQUIPMENT

Equipment required for a sphincterotomy includes a side-viewing duodenoscope to examine the duodenum and identify the papilla and a cannula which is passed into the common bile duct in order to fill the duct with radiopaque iodine contrast. A number of different cannulas are now available which improve the ability to achieve successful cannulation. Endoscopic papillotomes are available in a number of forms with different lengths and shapes of the exposed wire. These are valuable recent additions which have greatly facilitated the procedure. An electrosurgical unit is required to provide electrocautery current when the sphincter is cut. Backup equipment is needed at all steps of the procedure in case there is any instrument failure. The most recent development in this area is the availability of various stenting polyvinyl tubes which can be passed through obstructing tumors or benign strictures to allow flow of bile. Their placement generally requires an initial sphincterotomy.

INDICATIONS AND CONTRAINDICATIONS FOR THE PROCEDURE

Indications for endoscopic sphincterotomy include the presence of common bile duct stones, either before or after the gallbladder has been surgically removed. Common bile duct stones are usually removed when the gallbladder is still in place only in patients at high risk for surgery. Patients at normal risk for surgery are generally treated by surgical removal of the gallbladder and removal of the common duct stone. Accumulated data indicate that most patients who have common duct stones removed endoscopically, even with the gallbladder intact, do not have further symptoms within the short-term period of 2-3 years. The percent of patients requiring subsequent cholecystectomy is around 5%. With these data available, there will be continuing extension of the use of endoscopic sphincterotomy for common bile duct stones in patients with an intact gallbladder. The procedure is used for papillary stenosis, an entity in which the opening of the biliary and pancreatic ducts into the duodenum is compromised. When carefully defined, 70-80% of the patients having sphincterotomy performed for this condition are relieved of their symptoms. Patients with carcinoma of the ampulla who are not candidates for surgical resection may also be treated by this technique.

Contraindications to the procedure are few and include uncooperative patients, uncorrectable coagulation defects, and obstruction of the proximal stomach or duodenum.

UTILIZATION

The primary indication for endoscopic sphincterotomy is for removal of retained common duct stones. Approximately 600,000 cholecystectomies are performed each year in this country. Recurrent common duct stones develop in 5-10% of these patients at some time in the future. A success rate of 90% can be expected from endoscopic retrograde sphincterotomy, avoiding the need for surgery in 2,700-5,400 patients. Because this is a technically difficult procedure, it is not uniformally available throughout the country and many common bile duct stones are therefore still being removed surgically.

RESULTS OF ENDOSCOPIC SPHINCTEROTOMY

The success rate of the procedure approaches 90%, with accomplishment of the sphincterotomy and removal of the common bile duct stones. The complication rate is consistent throughout the world and ranges from 6.5% to 10%, with a mortality rate of approximately 1.5%. This is significantly lower than the mortality or complication rate of surgery. Complications consist of bleeding, pancreatitis, perforation, cholangitis, basket entrapment, and medication reactions. The most common complication is pancreatitis, which is generally mild, followed by bleeding, which may be mild or severe. The majority of the deaths in most series result from bleeding.

Complications and mortality of surgery are about 3 times that of endoscopic sphincterotomy.[8,9]

COST ANALYSIS

Endoscopic sphincterotomy requires approximately 2 days in the hospital, compared to approximately 8 days following surgery.

The cost of medical care varies widely throughout the nation. A brief review of one hospital in Minnesota showed the following total costs for 5 consecutive, uncomplicated cases of surgical and endoscopic removal of common bile duct stones:

Surgical Removal of CBD Stones	**Endoscopic Removal of CBD Stones**
$5,452	$1,626
5,843	1,669
6,105	1,979
7,868	2,016
7,989	2,643
(Mean) $6,651.40	(Mean) $1,986.60

Although these figures may vary around the country, the relative values are probably constant.

COST BENEFIT

The direct cost for the medical care of the two procedures is considerably less for endoscopic sphincterotomy. No allowance was made for differences in time lost from work and patient discomfort. This procedure clearly has a high cost-benefit ratio and should be encouraged as the method of choice for removal of common bile duct stones.

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Endoscopic Treatment Miscellaneous

Percutaneous Endoscopic Gastrostomy

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INTRODUCTION

Percutaneous endoscopic gastrostomy (PEG) was introduced in 1980 as an alternative to laparotomy for the performance of gastrostomy in patients with disease or trauma that interferes with normal swallowing. Percutaneous endoscopic jejunostomy is an extended application of percutaneous gastrostomy that is utilized when gastrostomy feedings pose an inordinate risk of aspiration or if simultaneous gastric decompression is desired. The comments and results concerning percutaneous gastrostomy also apply to percutaneous endoscopic jejunostomy.

PROCEDURE AND DESCRIPTION

The patient is placed on the endoscopy table in the supine position. The pharynx is sprayed with topical anesthetic and intravenous sedation is administered. The abdomen is prepared with betadine solution and draped in a sterile fashion. The endoscope is passed into the esophagus, and the esophagus and stomach are inspected. The room lights are dimmed to allow the assistant to look for transillumination of the abdominal wall by the light of the endoscope. Transillumination indicates close contact between the gastric and abdominal walls. The assistant then chooses an entry site at the point of transillumination. He applies intermittent finger pressure to that site while the endoscopist observes the interior of the stomach. The endoscopist sees clear and unmistakable indentation of the gastric wall when finger pressure is correctly applied to the entry site. After the entry site is determined, several milliliters of local anesthesia are infiltrated into the skin and subcutaneous tissue at this point. A #11 scalpel blade is used to make an incision in the skin. The assistant thrusts an intravenous cannula through the abdominal and gastric walls. A wire snare is looped around the needle and is then tightened around the cannula close to its emergence from the gastric mucosa. After the snare has been secured, the metal stylet is removed from the cannula. A 60" long #2 silk suture is then threaded by the assistant through the cannula into the stomach. After several inches of the suture have passed into the stomach the snare is loosened and allowed to fall away from the catheter and onto the silk itself. It is then tightened again and the endoscope-snare-silk complex is removed from the stomach. The silk, now exiting the patient's mouth, is securely tied to a suture that has been placed in the distal at the end of the gastrostomy tube and the tube is liberally lubricated. The assistant applies traction on the abdominal end of the silk. The gastrostomy tube proceeds, in a retrograde fashion, down the esophagus into the stomach,a nd out the abdominal wall.

After several inches of the tube have emerged from the abdominal wall, the endoscope is reinserted. The endoscopist then instructs his assistant to continue to pull on the abdominal end of the tube until the crossbar behind the head of the catheter just meets the gastric mucosa. An outer crossbar is then applied, completing the procedure.

EQUIPMENT

Any standard adult or pediatric gastroscope may be used to perform PEG. A snare which will pass through the biopsy channel of the instrument must also be available.

Gastrostomy tubes may be fashioned from available materials such as standard #16 or #18 French mushroom catheters in combination with rubber tubing and plastic intravenous cannulas. More recently, a number of companies have made completed catheters commercially available. The more notable of these, by such companies as American Endoscopy, Microvasive, and Wilson-Cook, have included kits with all the needles and suture material required for the procedure. In addition, the tubes themselves have shown slow but progressive improvements over the past three years.

INDICATIONS/CONTRAINDICATIONS FOR THE PROCEDURE

Indications for percutaneous gastrostomy include inability to swallow secondary to neurological impairment, oropharyngeal and esophageal neoplasia, facial trauma, prolonged gastric decompression, and as a route for supplemental feedings. Patients should demonstrate a potential for sustained response to nutritional support. Previous abdominal surgery is not a contraindication to the procedure; however, proximity to surgical scars should be avoided when selecting an entry site, and prior subtotal gastrectomy requires more caution in delineating the puncture site prior to entry. The procedure is also appropriate when gastrostomy is needed for long-term gastric decompression. In such cases, it may be modified to a percutaneous endoscopic jejunostomy to provide concomitant jejunal feeding and gastric decompression. The procedure is inappropriate in individuals with rapidly deteriorating medical conditions since a nasogastric tube may provide the same result over a short period.

UTILIZATION

The most common indication for percutaneous endoscopic gastrostomy is inability to swallow secondary to cerebrovascular accident (stroke).

Endoscopic Treatment Miscellaneous

Percutaneous Endoscopic Gastrostomy

JEFFERY L. PONSKY, M.D.

Stroke continues to be extremely prevalent in this country and a major cause for nursing home confinement of patients. Though PEG is a new technique, its popularity has grown rapidly owing to its relative ease, lower cost and great utility compared to surgical gastrostomy in the feeding of such patients. The risk of aspiration is less and patient comfort is greater with PEG than with nasogastric tube feedings.

RESULTS OF ENDOSCOPIC THERAPY

Several groups of investigators have published results of their experience with percutaneous endoscopic gastrostomy. Complication rates range from 5-15%, and procedure-related mortality rates have been very low. The most commonly occurring complications have been infections in the soft tissues surrounding the tube and leakage around the tube. These are usually treated by conservative means with good results. More serious complications, such as separation of the stomach from the abdominal wall, gastrocolic fistula, and necortizing fasciitis have been reported, but have occurred with a very low frequency. Pneumoperitoneum following PEG has been found to occur frequently but is usually of no clinical consequence. Comparison of these series with previous and currently reported results of surgical gastrostomy reveal percutaneous gastrostomy to be as safe and effective as classical surgical gastrostomy. In addition, the need for laparotomy is obviated. Indeed, the utilization of gastrostomy for feeding purposes has been greatly increased by the ease, availability and overall effectiveness of percutaneous gastrostomy.

COST ANALYSIS AND BENEFIT

Percutaneous gastrostomy is more cost effective than surgical gastrostomy. Although comparative studies of cost are few, those which have been performed reveal that percutaneous gastrostomy reduces cost by:

1) Reducing or eliminating operating time and operating room fees
2) Reducing or eliminating anesthesia costs
3) Reducing length of hospitalization
4) Reducing complication rates

One study, by Russell, et al, found the total cost of operative gastrostomy to be $2,674, compared to $510 for the percutaneous procedure. Time to initiation of feedings was shorter in the percutaneous group. The average physician fee for operative and percutaneous gastrostomy varies with the individual physician, his specialty and geographic location. In general, the physician fees for operative and endoscopic gastrostomy have been comparable and range from $400 to $1,000.

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Esophageal And Gastric Foreign Bodies — Endoscopic Removal

WILLIAM A. WEBB, M.D.

INTRODUCTION

In the United States, 1500 people die annually of foreign bodies of the UGI tract. Most foreign bodies (80%) occur in pediatric age groups, followed by edentulous adults, prisoners, and psychiatric patients. Most of these objects (80-90%) pass spontaneously; 10-20% have to be removed endoscopically; and about 1% require surgery. When a foreign body is ingested, Koch feels that 80% will enter the GI tract and 20% will go into the tracheobronchial tree. In our experience, 92% enter the former and only 8% the latter.

EQUIPMENT

Both rigid and flexible endoscopes can be used for removal of foreign bodies. Morbidity rates well below 1% with both types of instruments, but in the hands of the average physician, the flexible endoscope is safer. It should be noted, however, that the instrument of choice is usually determined by the training of the individual endoscopist.

For foreign bodies at the level of the pharynx or crico-pharyngeus muscle we use the open rigid laryngoscope (anesthesiologist type) and a surgical grasping clamp (Kelly). For all other forgeign bodies of the esophagus, stomach, and duodenum we use the flexible endoscopes. The rigid esophagoscope can be used effectively, as noted, in dealing with meat and sharp objects. It is also a less expensive instrument.

The advantages of the flexible instrument are numerous:

1) Safer in average hands;
2) Less post-procedural discomfort;
3) No general anesthesia required;
4) Built-in air insufflation and suction, as well as magnifying optics;
5) Examination of the stomach and at least part of the duodenum possible;
6) More cost effective, with no general anesthesia or recovery room required.

The newer flexible panendoscopes with diameters of 9.5-11 millimeters are ideal for removing foregin bodies. Their 2.8 millimeter operating channels allow the easy passage of polypectomy snares and alligator foreign body retrieval forceps (Olympus) which form the backbone of the therapeutic armamentarium.

INDICATIONS AND CONTRAINDICATIONS FOR PROCEDURE

Any foreign body of the hypopharynx or esophagus should be removed. Not all foreign bodies of the stomach need be. For example, 80% of coins entering the stomach will pass without difficulty. On the other hand, sharp and pointed foreign bodies, such as razor blades, should be removed because about 15% will perforate the bowel.

There are no absolute contraindications to foreign body removal, although some, such as the large foreign body, are more safely removed surgically than endoscopically. Foreign bodies usually constitute a semi-emergency or emergency state and must be dealt with immediately. The longer a foreign body remains in the gastrointestinal tract, the greater chance that a complication will occur.

PROCEDURE DESCRIPTION

Specific foreign bodies, such as coins, meat, sharp and pointed foreign bodies, button batteries, and cocaine, need to be discussed in greater detail.

COINS

One rarely sees problems with the ingestion of a dime, for it is usually the larger coins that lodge at the level of the cricopharyngeus muscle or just below it. A-P and lateral radiographs of the neck should be obtained to determine if the coin (or any radiopaque foreign body) is in the trachea or the esophagus. In the trachea, the A-P view will reveal the edge of the coin, while the flat surface will be seen on the lateral view. The reverse is true in the more posteriorly located esophagus, with the flat surface being seen on the A-P and the edge being seen on the lateral radiograph.

In infants and children, radiographs from the base of the skull to the anus should be made to determine if more than one foreign body is present. The single most important thing to remember in managing coins and other foreign bodies at the level of the cricopharyngeus is to *maintain an airway at all times*. For this reason, we remove them under general anesthesia with an endotracheal tube. After induction of anesthesia, the coin can often be grasped with a clamp, using a rigid laryngoscope. If this is not successful, flexible endoscopy is performed and the coin grasped with alligator-type forceps or a polypectomy snare. We had great success early in our experience with the latter when using a 9.5 millimeter flexible endoscope. The newer 9.5-11 millimeter endoscopes have larger operating channels and allow grasping forceps to be passed without difficulty. We now use this method almost exclusively. If the patient does not have an endotracheal tube, the Trendelenburg position should be used to keep the coin out of the trachea. We do not use the Foley catheter technique because one does not have control of the foreign body as it is removed. A magnet is not used because the cricopharyngeus muscle tends to knock the coin loose. If a child has a coin lodged in the esophagus and it passes spontaneously, it is not necessary to perform endoscopy unless it is a recurrent episode.

MEAT

There is rarely a true emergency when managing foreign bodies of the UGI tract, but one is the "cafe coronary", or when a large piece of meat is impacted at the level of the cricopharyngeus and cervical esophagus with anterior pressure on the trachea causing respiratory obstruction. This patient is usually seen outside the hospital environment, and one must act quickly. The finger can be used to dislodge the meat, or a fork can be used to hook it. The Heimlich maneuver is also useful in this situation.

A patient that presents with salivation has esophageal obstruction and should be endoscoped within a short period of time to prevent tracheal aspiration. Meat lodged in the esophagus without salivation is not an emergency and may be relieved with sedation and glucagon. The patient should then be endoscoped to determine the cause of obstruction. Carcinoma is rarely the cause.

We do not use papain since there have been reports in the literature of lethal complications. Also, aspiration of the papain from an obstructed esophagus, with resulting chemical pneumonitis, must be considered.

If flexible endoscopy is performed soon after ingestion, the meat can be removed easily as a single unit, using a polypectomy snare. However, if the meat has started to fragment, it becomes more difficult to remove, and flexible instruments must be withdrawn and reinserted repeatedly, or an overtube must be used. In this situation, rigid esophagoscopes have the advantage of allowing endoscopist to pull the fragments through the endoscope. We have found it very helpful to work a flexible pediatric endoscope past the obstructing meat and into the stomach. In this way, a stricture, if present, can usually be dilated with the endoscope so that the instrument can then be pulled back proximal to the meat and the bolus gently pushed into the stomach. I believe that hydrostatic balloon dilators of the "through the scope" type will begin to play a role in the management of foreign bodies of the UGI tract, especially meat impaction. The balloon can be passed distal to the meat, inflated, and the meat disengaged. The commonly occurring stricture can be evaluated and, if necessary, dilated with the balloon. The meat can then be gently pushed into the stomach with the endoscope.

If esophageal pathology is present, endoscopic assessment is completed, and if a peptic stricture is present and there is not too much reaction or edema from the foreign body, dilation is carried out immediately.

Routine radiographs or barium studies are not needed. Barium actually obscures the field and makes the job of the endoscopist more difficult.

SHARP AND POINTED FOREIGN BODIES

These foreign bodies can be very challenging and difficult to manage but fortunately they are not common. It is important to be extremely careful not to make the situation worse or to cause a complication, such as a perforated esophagus, that could be lethal. In this day of rapid transit, a patient can easily be moved to a center with an experienced endoscopist. It should not be considered a defeat to have to remove a foreign body surgically, for this is sometimes the safest means.

The open safety pin always represents a major problem. It is wise to remember Jackson's axiom, "Advancing points puncture; trailing ones do not". If this foreign body is in the esophagus with the open end proximal, it is best managed with the flexible endoscope by pushing the pin into the stomach and then grasping the hinged end and pulling it out first.

The razor blade is also a traumatic experience both to the patient and to the endoscopist. It is best managed with the rigid esophagoscope by pulling the blade into the instrument. It can also be managed with the flexible endoscope and overtube, especially if the blade has reached the stomach.

Sharp or pointed foreign bodies passing through the stomach into the small bowel represent a special concern because 15-30% will eventually perforate the bowel. Therefore, the patient should be started on a bowel prep. Daily x-rays should be taken to follow the progress of the foreign body. If the foreign body fails to progress for three to four days, or the patient becomes symptomatic, surgical intervention is usually indicated.

SPECIAL FOREIGN BODIES

The emphasis in modern society on technology and pleasure has resulted in problems with two special types of foreign bodies — button batteries and cocaine. The button battery industry has seen great growth because of hand calculators and watches. If ingested, they are not usually a problem unless they are greater than two centimeters in diameter. Once they get to the stomach, they will usually pass spontaneously. However, if lodged in the esophagus (usually cervical), fatal complications with perforation can occur. These batteries should

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be managed just as a coin, but can be more difficult to grasp because of the smoothness of the surface.

Cocaine trafficking has produced an interesting and difficult problem. A packet containing a large amount of cocaine will often be swallowed by a person to prevent detection — a so-called "body bagger". If the packet ruptures, it can be fatal. No attempt should be made to remove these packets endoscopically from the upper or lower GI tract. It is usually best to remove them surgically.

In removing difficult foreign bodies, time spent in forethought and planning will make extraction easier. These patients should also be treated with intravenous antibiotics prior to the procedure. If the foreign body can be duplicated and evaluated with a "dry run", the procedure will be easier and safer.

RESULTS OF ENDOSCOPIC THERAPY

From December 1975 to October 1985, we managed 110 foreign bodies which were treated as follows: 17 with the rigid endoscope, 90 with the flexible endoscope, and two surgically. (A straight pin could not be found in the stomach containing food and was subsequently passed spontaneously.) There was no morbidity or mortality. In the age group one to ten years, there were 26 patients (17 coins), while the age group 11 to 88 years had 84 patients (55 meat).

UTILIZATION

Children most often ingest coins, toys, crayons, and ballpoint pen caps, while adults commonly tend to have problems with meat and bones. There will often be a second foreign body present when one is known to have been ingested. Up to 2,533 foreign bodies have been recorded in the stomach of a single patient. Recurrent episodes of foreign body ingestion may occur, especially in prisoners, psychiatric patients, and patients with a peptic stricture or lower esophageal ring. Ten percent (10%) of the series reported by Payne had recurrent foreign bodies.

Objects thicker than two centimeters and longer than five centimeters tend to lodge in the stomach. It is our experience that some long objects tend to hang up in the duodenal sweep. Perforations occurring in this area may involve the right kidney.

COST ANALYSIS AND COST BENEFIT

The cost-effectiveness of flexible endoscopy is a very significant factor in this era of rapidly spiraling medical costs. Containing these costs should be an important consideration in the recommendation of every medical procedure, providing that the patient's medical care and well being are not compromised.

Flexible esophagoscopy with removal of a foreign body (CPT code number 43215) would cost as follows at our institution:

$ 29	Use of outpatient surgery
125	Use of endoscopy unit
425	Physician's fee
$579	Total

Rigid esophagoscopy and foreign body removal, using general anesthesia would cost as follows:

1 425	Use of operating room
298	General anesthesia
369	Recovery room
425	Physician's fee
$1,517	Total

One night of hospitalization would probably be needed, for an additional charge of $545 (average cost per day), with the resulting total being $2,062. Thus, the cost of removing a foreign body of the esophagus with a flexible endoscope is 62% more cost-effective than with the rigid instrument, without overnight hospitalization, and 72% more cost-effective with overnight hospitalization.

The cost differential in the removal of a foreign body from the stomach is even more impressive. The rigid endoscope will not reach the stomach, and if a foreign body must be removed (such as a sharp or pointed type or a nine-volt battery), it is necessary to resort to open surgery if flexible endoscopy is not available or is not successful. The cost of removing a foreign body of the stomach (CPT code number 43247) with the flexible endoscope is the same as for the esophagus ($579). The cost of removing the foreign body surgically through a gastrostomy, with a five-day hospitalization, would be as follows:

$ 652.	Use of operating room
390.	General anesthesia
369.	Recovery room
982.	Surgeon's fee
245.	Surgical assistant's fee
$2,638.	Total

Five days of hospitalization ($2,725) would bring this figure to $5,363. Therefore, flexible endoscopic removal of a foreign body of the stomach is 89% more cost-effective than surgical removal.

One must also consider the time lost from work after the surgical procedure. A minimum would be four weeks. For example: the absence of a laborer, earning $7.60 per hour, for one month would cost the company $1,300. Fringe benefits, such as sickness benefits, would cost an additional $1,000, for a total of $2,300 for the month. If the employee had to be replaced, it would cost an additional $1,300, for a total of $3,600. (These are average figures compiled from four industries in our area.) Therefore, the total cost for transabdominal surgery could be as high as $9,163.

From these figures, it is easy to see the cost containment impact that flexible endoscopy has had on the management of foreign bodies of the upper gastrointestinal tract.

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Glossary Of Medical Terms

Abdomino-Perineal Resection: Resection of the rectum, anus and rectosigmoid colon and creation of a colostomy; surgery performed for low rectal cancer

Alligator Forceps: A grasping instrument with teeth used in the endoscopic extraction of foreign bodies

Ampulla of Vater: A nipple-like excrescence where the biliary and pancreatic ducts enter the duodenum

Analgesic: A drug that reduces or relieves pain

Anastomotic: Occurring at the site of surgical connection of two tubular structures

Anesthesiologist: A physician specialist who administers anesthesia, usually for the purpose of performing surgery

Angiography: The x-ray visualization of blood vessels after injection of a radioopaque substance

Angioma: A swelling produced by dilated blood vessels (pleural: angiomata)

Anorexia: Loss of appetite

Antacids: Drugs taken orally which neutralize stomach acid

Anterior Resection: Resection of part of the rectum and sigmoid colon through a low abdominal incision

Antibiotic: A drug which kills or suppresses the multiplication of bacteria

Antrectomy: Surgical resection of the terminal portion of the stomach, the antrum, for the treatment of peptic ulcer disease

Aortic Aneurysm: An abnormal dilatation of the main arterial trunk leaving the heart, resulting from disease of the vessel wall

A-P Radiographs: X-ray picture taken front to back

Arteriovenous Malformation: Abnormal communication between an artery and vein producing dilated vessels

Artery: A blood vessel carrying blood at high pressure from the heart to an organ or tissue

Aspiration: Withdrawal by suction, usually of liquid; the taking of foreign material into the lung during inspiration

Asymptomatic: Absence of symptoms, which are subjective manifestations of disease

Bacteremia: Bacteria in the blood stream

Barium: Dense, radioopaque liquid suspension used as contrast agent in some gastrointestinal x-ray studies

Basket: A device on the end of a wire used to capture and extract stones from the bile ducts

Betadine: A chemical disinfectant which can be applied to the skin

Bile: Fluid secreted by the liver into the bile ducts

Bile Duct (biliary tree): The tubes or ducts which conduct bile from the liver to the duodenum

Biliary Endoprosthesis: A tube placed in a narrowed or blocked bile duct to relieve obstruction to bile flow

Biopsy: Procurement of a small sample of tissue for analysis

Bipolar Electrode: A cautery tip containing both poles of an electric circuit; current flows from one pole through tissue to the other pole

Bolus: A soft mass of chewed food

Bougie: A tapering or cylindrical instrument introduced into a tubular passage of the body, such as the esophagus, for the purpose of dilating a narrowing

Bowel Prep: Cleansing of the colon prior to colonic surgery, colonoscopy, or barium x-ray studies

Cannula: A small tube for insertion into a body cavity, duct, or vessel

Cecum: The sac-like part of the large bowel located at its front or proximal end; contains the entry of the appendix and the small intestine

Cervical Esophagus: That part of the esophagus that passes through the neck

Cholangitis: Inflammation or infection of the bile ducts

Central Venous Nutrition: Nutrition administered through a catheter placed in a large, centrally located vein

Cholecystectomy: Surgical removal of the gallbladder

Cholestasis: Obstruction to the flow of bile

Cimetidine: A drug which inhibits acid secretion by the stomach

Cirrhosis: A disease of the liver consisting of scarring or fibrosis and nodular changes which may severely impair its function

Chemotherapy: Treatment of cancer with drugs

Clot: Coagulated or solidified blood

Coagulation: To be formed into a viscous or coherent mass

Coagulopathy: Abnormality of the blood which interferes with its normal clotting

Colon: Large intestine

Colonoscopy: Examination of the lumen of the colon or large bowel using an endoscope

Colostomy: Surgical creation of an artificial opening from the colon

Glossary Of Medical Terms

Common Duct: The main bile duct formed by union of the right and left hepatic bile ducts; empties into the duodenum

Contraindications: Reasons why a test or treatment might be harmful to a patient's health or well-being and therefore should not be implemented

Contrast Agent: A substance, opaque to x-rays, which is introduced into an organ, duct or vessel for the purpose of defining its size, shape, or location radiographically

Controlled Studies: Scientific studies which employ comparison with a similar sample or group not manipulated by the variables in question

Cost-Benefit: Economic analysis of benefit that assigns a numerical value to the effectiveness of a measure

Cost-Effectiveness: Economical in terms of tangible benefits produced by money spent

Crico-Pharyngeous Muscle: A horizontal muscle located at the upper end of the esophagus

Crohn's Disease: A disease of unknown etiology causing inflammation of part of the intestines and sometimes the stomach

Debulking of Tumor: Resection of as much tumor as possible when complete removal is not feasible

Decompression: Relief of pressure or obstruction

Defecation: To discharge feces from the bowels, usually through the anus

Demerol (Meperidine): A narcotic drug that reduces pain; an analgesic

Diagnostic: Capable of identifying the cause of signs or symptoms of disease

Dialysis: Treatment of renal failure or drug/toxin poisoning using the "artificial kidney" machine

Disinfection: Destruction of harmful microorganisms, usually by exposure to a chemical

Diverticula: A pocket or abnormal sac-like opening from a hollow organ such as the stomach or intestine

Duodenal Sweep: The C-shaped curve of the duodenum

Duodenoscope: A side-viewing flexible endoscope inserted into the duodenum; used to perform studies and procedures on the biliary and pancreatic ducts

Duodenum: The first part of the small intestine

Dumping Syndrome: A complex of symptoms (nausea, pain, weakness, flushing) produced by the rapid passage of food into the small bowel after gastric resection or surgery

Dysmotility: Abnormality of the muscular contractions of the gut interfering with normal movement of its luminal contents

Dysphagia: Difficulty swallowing food or liquid

Edema: Increased tissue fluids; swelling

Edentulous: Lacking teeth

Efficacious: Having the ability or power to produce a desired effect

Elective: Not an emergency

Electrocautery: Thermal destruction or coagulation of tissue by passing a high frequency electric current

Electrode: A terminal of an electric source through which electrical energy may pass when a circuit is completed

Emaciated: Thin; physically wasted

Encephalopathy: Disease of the brain

Endoscope: An instrument used to examine the inside of any part of the body

Endoscopist: A physician who performs examinations or provides treatment using an endoscope

Endoscopy: The performance of examinations or therapeutic procedures using an endoscope

Endotracheal Tube: A tube passed through the mouth or nose into the trachea to provide a free passage for air into the lungs

Erosion: The loss or disruption of superficial or surface material or tissue

Esophago-Pulmonary Fistula: An abnormal connection between the esophagus and the lung

Esophagoscope: Instrument used to examine the lumen of the esophagus; rigid or flexible

Esophagus: The tube-like portion of the digestive tract which transmits food and fluid from the oral cavity to the stomach

Etiology: The cause

Extrahepatic Biliary Tree: Bile ducts outside or beyond the liver

Fiberoptic Endoscope: An endoscope in which light and a visual image is transmitted along bundles of tiny glass fibers

Fibrosis: Scarring; production of dense, firm tissue in response to previous tissue damage or disease

Flexible: Capable of being bent without injury

Fluoroscopically: Showing the internal structure of an opaque object by means of x-rays

Foley Catheter: A tube with an inflatable balloon at the tip used to extract urine from the urinary bladder

Glossary Of Medical Terms

Foreign Bodies: An object, usually from an external source, in an abnormal location in the body

Fulguration: Destruction of tissue by applying an external energy source

Gallbladder: A sac-like structure connected to the main bile duct where bile secreted by the liver is stored

Gastrectomy: Surgical removal of all, or part of, the stomach

Gastric Bypass: Treatment of obesity which involves the surgical closing or bypassing of part of the stomach in order to decrease the capacity for food ingestion

Gastroenterologist: A specialist in internal medicine who deals with disorders of the gastrointestinal tract and associated organs

Gastroenterostomy: Surgical creation of an artificial opening between the stomach and small bowel

Gastrointestinal: Pertaining to all, or part of, the digestive or alimentary tract (esophagus, stomach, small and large intestine)

Gastrostomy: Creation of an artificial opening from the stomach

General Anesthesia: Anesthesia which renders the patient unconscious

Glucagon: A drug hormone which decreases gastrointstinal muscular activity

Guidewire: A flexible wire positioned in an organ, vessel, or duct for the purpose of directing the passage of a larger device threaded over or along its length

Heimlich Maneuver: A first aid measure employing vigorous compression of the abdomen used to treat acute upper airway obstruction by a foreign body

Hematocrit: Fraction of the blood occupied by red blood cells

Hemoccult Test: A commercially produced slide test for fecal occult blood

Hepatitis: Inflammation of the liver, usually caused by a viral infection or a toxin

Hemorrhage: Bleeding; loss of blood

Hemostasis/Hemostatic: The stoppage of bleeding

Histologic: The study of the microscopic structure of a tissue

"Hot Biopsy": Procurement of a biopsy using an endoscopic biopsy forceps which allows simultaneous electrocauterization of the site; usually used for the resection of small polyps

Hydrostatic Balloons: Balloons used to dilate a narrowing or stricture which are inflated with water

Hypopharynx: The lowest part of the pharynx, adjacent to the entry into the esophagus

Immunocompromised: Reduced natural ability of the body to fight infection, most commonly due to drugs or disease

Impaction: Lodgement of something in a body passage, such as stones in the bile duct or feces in the bowel

Indications: Reasons for implementing a test or treatment

Intramural: Within the wall of an organ such as the intestine

Intravenous: Administered into a vein through a needle or catheter

Invasive: A procedure which is usually complex and requires appreciable penetration into internal areas of the body

Iron Deficiency Anemia: Anemia due to lack of iron in the body, usually the result of previous loss of blood

Jejunostomy: Creation of an artificial opening from the jejunum (middle part of the small bowel)

Laparotomy: Surgical incision into the abdominal cavity

Laryngoscope: An instrument used to examine the upper passage to the lung, the larynx

Laser: A device that amplifies light waves and concentrates them in a narrow, very intense beam of energy

Lesions: A circumscribed abnormality in a structure or organ due to damage or disease

Local Pharyngeal Anesthesia: Reduction of sensation of the pharyngeal lining produced by a topically administered anesthetic drug

Lower Gastrointestinal: Involving the terminal small bowel, colon, or rectum

Lower Esophageal Ring: An abnormal rim of tissue which may partially block the lower esophagus

Lumen: The cavity or bore of a tubular organ

Malignant: Tending to produce death or deterioration; usually refers to cancer

Mallory-Weiss Tear: A tear in the inner lining of the lower esophagus caused by vigorous vomiting

Mediastinitis: Inflammation or infection of the central area of the thorax, the mediastinum

Medical Management: Treatment which does not require surgery or special invasive procedures

Glossary Of Medical Terms

Melena: The passage of dark, tarry stools due to the presence of blood altered by the intestinal juices

Metastatic: Spread from site of origin to other locations; usually refers to spread of cancer

Monopolar Electrode: A cautery tip containing one pole of an electrical circuit; current flows from the electrode tip through the body and back through a ground plate

Morbidity: Incidence of disease

Morbid Obesity: Sufficiently overweight to impair health; markedly obese

Mortality: Death, or frequency of death

Mucosa: The inner-most layer of the gastrointestinal tract; lining of the gastrointestinal lumen

Mucous Membranes: The internal, mucous-secreting lining of the gastrointestinal tract and some other organs

Nasogastric: Involving a tube or device passed through the nose into the stomach

Necrotizing Fasciitis: Inflammation and destruction of one of the deeper layers of the abdominal wall

Neoplasm: A tumor or new growth of tissue serving no physiologic function; may be benign or malignant

Neuromuscular Disorders: Abnormalities of muscular contraction resulting from derangement of either nervous control or muscular function

Obstructive Jaundice: Increased blood bilirubin causing yellow skin due to blockage of the bile ducts

Occult Bleeding: Abnormal loss of blood too little to be identified visually

Outpatient: A hospital patient who is not admitted to a hospital bed

Overtube: A hollow tube of sufficient diameter to fit over an endoscope, used to extract sharp or pointed foreign bodies

Pancreatitis: Inflammation of the pancreas

Panendoscope: A flexible endoscope capable of examining the esophagus, stomach, and proximal duodenum

Papain: A protease enzyme that digests meat or other protein substances

Papillary Stenosis: Narrowing of the opening of the bile and pancreatic ducts into the duodenum at the papilla of Vater

Papillotome: Spincterotome, a device used to cut the sphincter of Oddi

Pediatric: Having to do with children

Pediatric Endoscope: Endoscopes of smaller diameter designed for use in children

Peptic Stricture: Fibrotic narrowing of the esophagus due to reflux of acid-peptic juice

Peptic Ulcer: An excavated lesion of the internal layers of the stomach or duodenum caused in part by acid-peptic destruction of tissue

Peritoneal: Involving the internal lining of the abdominal cavity or the outer layer of abdominal organs, the peritoneum

Peritonitis: Inflammation or infection of the peritoneum, the internal lining of the abdominal cavity

Peptic/Pepsin: Referring to the digestive enzymes produced by the stomach which help break down food protein

Percutaneous: Passing through the skin

Periampullary Carcinoma: A cancer arising in the duodenum at the ampulla of Vater

Photocoagulation: Coagulation induced by light wave energy

Portal: The large vein carrying blood from the intestines and spleen to the liver

Postprandial: Following meals

Palliation: To decrease the intensity or severity of a disease or condition

Perforation: A hole in a hollow organ such as the stomach or intestine

Peroral: To give by mouth or pass through the mouth into the gastrointestinal tract

Pharynx: The portion of the alimentary or digestive tract situated between the oral cavity and esophagus

Pneumatic: Expandable by filling with air

Polyp: A projection or excrescence of tissue above the surface of a membrane

Polyvinyl Tubing: Flexible, clear plastic tubing commonly used to collect or perfuse fluid, or measure pressures in the gastrointestinal tract

Portal Vein Thrombosis: A clot formed in the portal vein

Portosystemic Shunt: Surgical creation of an artificial communication between the portal venous system and other veins

Post-Vagotomy Stasis: Decreased contractions and emptying of the stomach after surgical interruption of the vagus nerve for the treatment of peptic ulcers

Pneumoperitoneum: Air or gas in the abdominal cavity, usually seen on x-ray

Prognosticator: An observation useful in predicting outcome

Prokinetic Agent: A drug which stimulates or enhances muscular contraction or movement

Glossary Of Medical Terms

Prophylactic Treatment: Therapy used to prevent a possible or predicted disease or outcome

Prosthesis: An artificial device used to replace a missing part of the body

Pruritis: Itching

Pulmonary Emboli: A clot passing from a thrombosed vein to the lung

Pyloric Channel: The short passage through the opening between the stomach and small intestine

Pyloric Stenosis: Abnormal narrowing of the opening between the stomach and small intestine

Pyloroduodenal: Located in the opening between the stomach and the small intestine

Pyloroplasty: Surgical widening of the opening between the stomach and small intestine

Pylorus: The narrow opening between the stomach and small intestine

Radiographic: Involving the use of x-rays of x-radiation techniques

Radiologic: Involving the use of x-ray techniques

Randomized Study: A scientific study in which samples or subjects are assigned to different experimental groups by chance

Ranitidine: A drug that inhibits stomach acid secretion

Rectosigmoid: The part of the colon where the rectum and sigmoid colon meet

Rectum: The terminal part of the large intestine, extending from the sigmoid colon to the anus

Reflux: Passage of fluid in an abnormal direction, such as reflux of acid from the stomach into the esophagus

Renal: Involving the kidneys

Retrograde: Passing against or in the opposite direction of normal flow

Rigid Endoscope: An endoscope which cannot be bent

Saliva; Secretion of the salivary glands in the mouth or oral pharynx

Salivation: Secretion of saliva by the salivary glands

Sclerosant: Chemical used to obliterate varices

Sclerotherapy: Injection of a chemical for the purpose of obliterating varices

Sepsis: A toxic condition resulting from the spread of bacteria or their products from a focus of infection

SICU: Surgical intensive care unit; provides intensive care required immediately after surgery

Snare: An instrument containing a closable wire loop

Sphincter of Oddi: Muscle encircling the outlet of the common bile and pancreatic duct at the ampulla of Vater

Sphincterotome: Instrument containing an electrocautery wire-electrode used to perform endoscopic sphincterotomy

Spincterotomy: Cutting of the sphincter of Oddi in order to relieve obstruction of the bile and pancreatic ducts

Splenorenal Shunt: Surgical creation of an artificial communication between the splenic (spleen) and renal (kidney) veins

Stenosis: Abnormal narrowing or stricture

Stent: A hollow tube placed through a stricture for the purpose of relieving obstruction

Sterile: Completely free of microorganisms

Stomach: The bag-like portion of the digestive tract located between the esophagus and small intestine

Subcutaneous: Layer beneath the outer layer of skin

Submucosa: An internal tissue layer in the wall of the gastrointestinal tract

Supine: Lying flat on one's back

Supportive Treatment: Only that treatment needed to sustain the patient's status

Tamponade: To arrest flow by applying pressure or inserting a plug

Telangiectasia: Dilation of small or terminal blood vessels

Therapeutic: Capable of treating disease

Thoracotomy: Surgery involving opening or cutting into the chest or thoracic cavity

Trachea: Main trunk of the system of tubes by which air passes to and from the lungs

Tracheobronchial Tree: The tubes or passages which conduct air to and from the lungs

Trendelenburg Position: Supine position with the head lower than the feet

Transfusion: Administration of blood, usually to replace lost blood in a bleeding patient, or to correct anemia

Upper Gastrointestinal: Involving the esophagus, stomach, or proximal small bowel

Vagotomy: Surgical interruption of the vagus nerve to decrease nervous stimulation of stomach acid secretion

Glossary Of Medical Terms

Valium (Diazepam): A tranquilizer drug

Valvular Heart Disease: Malfunction of the heart due to diseased or damaged heart valves

Variceal Hemorrhage: Bleeding from varices

Varix: An enlarged and tortuous vein (pleural: varices)

Vasovagal Reaction: An abnormal reflex stimulation of the vagus nerve causing slowing of the heartbeat, decreased blood pressure, sweating, and sometimes fainting

Vein: A blood vessel carrying blood at low pressure from an organ or tissue to the heart

Villous: Microscopic structure characterized by long finger-like or hair-like projections from the surface

Visible Vessel: A identifiable blood vessel in the base of a peptic ulcer